INTERNATIONAL PATENT ISSUES: PROMOTING A LEVEL PLAYING FIELD FOR AMERICAN INDUSTRY ABROAD

HEARING

BEFORE THE

SUBCOMMITTEE ON
INTELLECTUAL PROPERTY,
COMPETITION, AND THE INTERNET

OF THE

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APRIL 26, 2012

INTERNATIONAL PATENT ISSUES: PROMOTING A LEVEL PLAYING FIELD FOR AMERICAN INDUSTRY ABROAD

THURSDAY, APRIL 26, 2012

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON INTELLECTUAL PROPERTY,
COMPETITION, AND THE INTERNET,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:12 a.m., in room 2141, Rayburn House Office Building, the Honorable Bob Goodlatte (Chairman of the Subcommittee) presiding.

Present: Representatives Goodlatte, Quayle, Chabot, Watt, Conyers, Chu, Deutch, Lofgren, Jackson Lee, Waters, and Johnson.

Staff Present: (Majority) Vishal Amin, Counsel; Olivia Lee, Clerk; and (Minority) Stephanie Moore, Subcommittee Chief Counsel.

Mr. GOODLATTE. Good morning. This hearing of the Subcommittee on Intellectual Property, Competition, and the Internet will come to order. And I recognize myself for an opening statement.

I will start by wishing you all a Happy World IP Day. Today we are holding a hearing on international patent issues, looking specifically at the problems that American companies face when seeking enforcement and using patents overseas. The Leahy-Smith America Invents Act was the first patent reform bill in over 60 years and the most substantial reform of U.S. patent law since the 1836 Patent Act. In light of the AIA's recent passage which maintains the U.S. patent system as the global standard, we need to now expand our focus and closely examine the adequacy and effectiveness of patent systems in foreign countries and whether they meet global trading standards. We need to evaluate whether they create a level or an unlevel playing field for American inventors.

Looking at recent history, today's hearing topic appears to be the first time in either the House or Senate that Congress has looked specifically at international patent laws in the context of intellectual property enforcement. As we will learn today, U.S. innovators continue to face patent-specific enforcement issues internationally. These global problems require real solutions. The ability to obtain timely decisions regarding patent applications as well as meaningful enforcement of patent rights go to the very heart of our innovative companies and their ability to compete on the global playing field.

Unfortunately, we have seen many foreign countries ignore real legal reforms and effectively create major barriers to trade for U.S. companies in the patent space. When asked why he robbed banks, Willie Sutton once said, "Because that is where the money is." And it appears that in the context of IP enforcement, foreign countries have been focusing their market-distorting actions right where the money is. From an economic and jobs perspective, company profits are driven directly by the goods or products that they can sell. And for patented innovations, many foreign countries are getting a free pass when it comes to the patent systems they have in place.

As more and more American companies expand their international presences and seek patent protection in foreign markets, these patent-specific harms have grown exponentially in their importance. Less than a decade ago, there were only a handful of companies that filed for patents abroad and faced these kinds of market access issues. Today nearly every innovative American company that sells patented products abroad is harmed in some way by these market-distorting actions.

This hearing is meant to shine a spotlight on these issues and encourage the Administration to expand the U.S. Government's efforts to do more and work to find real solutions to these unfair trade practices that distort the free market trade and end American jobs. For a range of innovative companies, from the pharmaceutical and biotech space to technology and manufacturing, the patents that they own or license form the foundation of their business. In the United States, we have worked to ensure a patent system that not only expeditiously reviews patent applications but issues quality patents that can be enforced through the courts and administrative proceedings. The U.S. patent system is designed to be fair, meeting our international obligations and not discriminating against any field of technology.

The same cannot be said of the patent systems and patents granted in many markets around the world. When American companies seek patent protection in foreign markets, they see their patent applications being held up, with patent pendency times approaching a decade in some cases. They see their patents subjected to unnecessary administrative hurdles. And even after going through these challenges they continue to face issues in foreign courts and administrative agencies to even bring their product into the local market.

When Nations go out of their way to devalue the intellectual property of America's innovative companies, they not only violate their international commitments but create a significant negative economic impact that hits the U.S. economy and domestic jobs.

This hearing is just a start. And as we work to make progress on these issues, we look forward to working with American innovators and industry to help identify specific concerns and issues so that the U.S. Government works with our trading partners to find solutions. We can ensure that the solutions reached are in line with compelling U.S. economic interests and job creation.

I look forward to both hearing from all of our witnesses on the issues that they have seen on the ground and also engaging in a discussion on how we can improve and correct the patent issues

that American industry faces abroad to promote U.S. manufacturing, technology, and innovation.

It is now my pleasure to recognize the Ranking Member of the Subcommittee, the gentleman from North Carolina, Mr. Watt.

Mr. WATT. Thank you, Mr. Chairman. And thank you for convening this important hearing—maybe among the most important hearings we could be having, although unfortunately about things we don't have absolute control over but need to evaluate nevertheless.

A little over 2 weeks ago on April 10, the Obama administration issued a report entitled, "Intellectual Property and the U.S. Economy: Industries in Focus." The report stands as the first of its kind backed by comprehensive investigation by the Federal agencies that share responsibility for safeguarding the interests of American industries, the Department of Commerce and the U.S. Patent and Trademark Office.

As we celebrate World IP Day today, this report reinforces the major contributions that all U.S. intellectual property-intensive industries make to the Nation's economy; specifically, after examining 313 American industries, the investigation identifies 75 industries as IP-intensive. These industries produce 27.1 million jobs for our citizens.

The report further concludes that a substantial share of IP-intensive employment in the United States was in trademark-intensive industries, followed by patent- and copyright-intensive industries respectively.

Intellectual property has played a major role in building American industry, largely because IP enforcement within the United States is strong. Unfortunately, American intellectual property does not always enjoy the same level of protection throughout the world. Other countries profit from an immense world trade of illicit goods and anti-competitive practices that violate the IP rights of U.S. rights holders. So while today we focus on patent-intensive industries and the challenges those industries face globally, we must remain ever vigilant in our effort to enhance America's standing in the competitive international market and to guard against unfair foreign encroachments on our intellectual property rights.

The annual Special 301 Report by the United States Trade Representative is scheduled for release next Monday, April 30. That report will identify those countries that continue to provide inadequate intellectual property protections for U.S. products and also highlight any progress that has been made. Inadequate protections can consist broadly of a lack of legal structure for protecting IP rights and inadequate penalties for IP crimes or poor enforcement of laws designed to protect rights holders.

We are fortunate to have here today witnesses from the pharmaceutical and technological industries to report to us firsthand some of the ongoing obstacles they face in foreign markets as well as two experts, including our former staff person Dr. Christal Sheppard, who have extensive experience evaluating these issues.

The bottom line, Mr. Chairman, is, we can have the most innovation, best protected intellectual property possible in the United States; but unless it is protected around the world in this inter-

national global environment in which we are operating, we are kind of swimming upstream always.

So I will conclude, Mr. Chairman, and allow the witnesses to update us on the current state of affairs for patent protection abroad and hopefully some suggestions also on how we may be able to strengthen those enforcements and patent protections in other parts of the world.

I yield back.

Mr. GOODLATTE. The Chair is pleased to recognize the Ranking Member of the full Committee, the gentleman from Michigan, Mr. Conyers.

Mr. CONYERS. Chairman Goodlatte, I thank you and the Ranking Member for putting this together. And its importance has already been stated by both of you. I agree completely.

Earlier this week, I began developing something that is related. And it is called the zero percent unemployment goal of this country, another very far-reaching attempt to come about full employment at another way. It has never been put together before. But that connects very directly into this hearing on international patent issues. So it gives me a chance to broach both of these topics and invite our witnesses to think about the interrelationship.

The economy, both nationally and globally, the economies of the world in the end all turn on how many people are gainfully employed. And we have now reached the point in our political maturation that we now realize that having a job is a right, a serious and important right. And the way our patent laws relate to this is of critical importance; what the Internet does, how intellectual property is regarded in each of these states.

So this Committee has a huge ongoing responsibility to begin to examine the systems in the rest of the world because we can't ask people to do what we would like them to do when we don't even know what they are doing. And that is going to task our staff and our resources going into the next Congress, for sure. And I think we are up to it. I think it is an exciting challenge that all ties into why we joined here today.

I did want to say one word about our witness Mr. Israel, who is here. I wanted to in particular welcome him to the Committee. I may be given the honor of introducing Christal Sheppard. So I will turn back my time and thank you very much.

Mr. GOODLATTE. Thank you, Mr. Conyers. And I have a feeling that request is going to be honored. And without objection, other Members' opening statements will be made a part of the record.

We have a very distinguished panel of witnesses today. Each of the witnesses' written statements will be entered into the record in its entirety. And I ask that each of you summarize your testimony in 5 minutes or less. To help you stay within that time, there is a timing light on your table. When the light switches from green to yellow, you have 1 minute to conclude your testimony. When the light turns red, it signals the witness' 5 minutes have expired. And before I introduce our witnesses, as is customary with this Committee, I would like to ask them to stand and be sworn.

[Witnesses sworn.]

Mr. GOODLATTE. Thank you. Be seated. Our first witness is Dr. Roy F. Waldron, Senior Vice President, Associate General Counsel

and Chief Intellectual Property Counsel at Pfizer. Dr. Waldron leads a team of Pfizer attorneys and professionals worldwide who procure patents, work closely with R&D business development, and the Pfizer business units and ensure enforcement of trademarks. He serves as the chair of the IP task force at PhRMA and is on the board of the Intellectual Property Owners Association. He joined Pfizer in 1999 from White & Case's IP practice group and was also previously an associate at Fish & Neave. Dr. Waldron has a JD from New York University School of Law, a Ph.D. in physical organic chemistry from Yale University, and a bachelor's degree from Dartmouth College.

Our second witness is the Honorable Chris Israel. Mr. Israel served as our Nation's first U.S. Coordinator for International Intellectual Property Enforcement during the administration of President George W. Bush. As the President's IP Coordinator, he was responsible for coordinating and leveraging the resources of the U.S. Government to protect American intellectual property rights at home and abroad. Prior to this, he served as Deputy Chief of Staff to Commerce Secretaries Don Evans and Carlos Gutierrez, where he assisted in the leadership and management of all major Commerce Department priorities, such as trade and economic policy. Mr. Israel also served as Deputy Assistant Secretary of Commerce for Technology Policy where he helped lead the Administration policy designed to maximize U.S. competitiveness and technological growth. Currently Mr. Israel is a partner at the American Continental Group. He received his bachelor's degree from the University of Kansas and an MBA from George Washington University.

Our third witness is Mr. Sean Murphy, Vice President and Counsel, International Government Affairs, at Qualcomm. Mr. Murphy manages Qualcomm's international public policy agenda, representing the company before branches of the U.S. and foreign governments, industry associations, and multilateral institutions like the OECD and APEC. Before joining Qualcomm in 2001, Mr. Murphy practiced law at Mayer Brown and served in the Office of the U.S. Trade Representative. He holds a bachelor's degree in political science from the University of California Santa Barbara, a master's degree from the University of Cambridge and a law degree from Georgetown University.

And our fourth and final witness has some close ties to this Committee and most especially to the Ranking Member of the Committee, so I will yield to Mr. Conyers for the purpose of an introduction.

Mr. CONYERS. Thank you very much, Chairman Goodlatte. I am going to put this in the record because it is far too long. And I know she didn't have anything to do with its preparation, but with the admiration of all of your former staff members and the Members of the Committee, I will just briefly summarize.

She is presently teaching law at Nebraska College of Law. But ironically, she started off as a scientist, at the University of Michigan and then finally to Cornell Law School and working on the Appeals Federal court, practicing in a large firm and then the United States International Trade Commission. So she brings a full circle

of expertise that is important in forming the views that she will present here today.

Dr. Sheppard, we are all here, on both sides of the aisle, very pleased to welcome you back as a distinguished witness.

[The information referred to follows:]

A. Christal Sheppard, Ph.D., J.D.

Biography

Dr. Sheppard is an Assistant Professor of Law at the University of Nebraska College of Law where she co-founded a program of Concentrated Study in Intellectual Property law.

Dr. Sheppard joined the University of Nebraska faculty in 2011, after over two decades of Science and Intellectual Property Law and Policy experience. Her successful career in intellectual property law and policy included her tenure as Chief Counsel on Patents and Trademarks for the United States House of Representatives Committee on the Judiciary where she was integral in many endeavors including the Smith-Leahy America Invents Act, the most comprehensive change to this nation's intellectual property laws in over 60 years.

Dr. Sheppard began her career as a scientist earning a M.S. and Ph.D. in Cellular and Molecular Biology from the University of Michigan. She is published in well-regarded scientific journals. After receiving a J.D. from Cornell University Law School and interning with Judge Radar at the Court of Appeals for the Federal Circuit and the Executive Office of the President's Office of Science and Technology Policy, she was a practicing attorney at the law firm of Foley & Lardner earning extensive experience in patent prosecution, client patent counseling and ligation. She then served in the Office of the General Counsel of the United States International Trade Commission working on Section 337 matters, arguing before the United States Court of Appeals for the Federal Circuit. In 2005, Dr. Sheppard also completed Harvard University's John F. Kennedy School of Government's Executive Education for Senior Managers in Government program.

Professor Sheppard teaches Patent Law; International Intellectual Property Law; Science and Law; and Legislation and the Political Process.

Currently Professor Sheppard is working on a variety of projects including an analysis of the effects of patent reform on the functioning of the Patent and Trademark Office (PTO) and the net effect of the Courts' expansion of patent law to new technologies such as software and biotechnology.

Ms. SHEPPARD. Thank you.

Mr. GOODLATTE. Thank you, Mr. Conyers. And Dr. Sheppard, we welcome you as well. We welcome all of you, and we will begin with Dr. Waldron.

TESTIMONY OF ROY F. WALDRON, SENIOR VICE PRESIDENT, ASSOCIATE GENERAL COUNSEL AND CHIEF INTELLECTUAL PROPERTY COUNSEL, PFIZER, INC., ON BEHALF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Mr. WALDRON. Good morning, Mr. Chairman and Members of the Subcommittee. Thank you for this opportunity to appear here today.

Mr. CONYERS. Turn it on.

Mr. WALDRON. Thank you for this opportunity to appear here today. My name is Roy Waldron and I am the Chief Intellectual Property Counsel for Pfizer. I am also the Chair of the Intellectual Property Task Force within the International Section of PhRMA, the Pharmaceutical Research and Manufacturers of America. It is in this capacity as chairman of that task force that I appear here today.

With your permission I would like to summarize our prepared statement and I request that our full written submission be included in the record in its entirety.

PhRMA represents the country's leading pharmaceutical research——

Mr. GOODLATTE. Dr. Waldron, you may want to pull that microphone closer to you. People will hear you better in the audience I think.

Mr. WALDRON. PhRMA represents the country's leading pharmaceutical research and biotechnology companies. U.S. biopharmaceutical research makes important economic contributions to the U.S. GDP, contributions likely to grow if the incentives and underpinnings for large-scale R&D investment remain intact. The U.S. biopharmaceutical sector supported a total of 4 million jobs in 2009, including more than 650,000 direct jobs. The U.S. biopharmaceutical industry also exported about $46 billion in goods in 2011, making it the sixth largest U.S. exporting industry for the year. Markets outside of the U.S. are fueling demand for innovative medicines due to their increasing economic growth and rising middle class. Both innovative medicines and generics play a critical role in the health of patients around the world. However, the innovation of new medicines depends on a respected and enforced intellectual property regime. Intellectual property protections spur the discovery of new medicines which later become generics.

Although strong intellectual property protections are provided in the United States, this is not true in many countries where the greatest growth potential for U.S.-developed innovative medicines is expected to occur in the future. Many of these countries' local biopharmaceutical companies are owned or connected to the government, if not supported by the government's industrial policies. The main competitive edge of the U.S. biopharmaceutical industry relative to these local businesses is the innovative nature of our products. However, while developing and testing a new medicine requires significant and risky investment of over $1 billion on average and over a development period of up to 12 years, local companies can copy medicines with little effort in a very short period of time. Without the legal principles and mechanisms in place which recognize and enforce patents effectively, local companies can mar-

ket copies immediately and obliterate our industry's innovative competitive advantage. Unsurprisingly, foreign governments as well as local companies resist the establishment of these IP principles and mechanisms.

We face three categories of patent-related barriers: lack of efficient, effective, and timely patent enforcement; problems with extreme delay in the grant of patents; and restrictive requirements and other locally imposed hurdles to patent grants. Some barriers are inconsistent with international law but are maintained to protect local interests. At the same time, these local interests, when doing business in the U.S., benefit from the effective and open U.S. patent system.

To move to a more level playing field, we urge the Subcommittee to, one, ensure that the Administration pursues strong intellectual property standards in free trade agreements, including the ongoing negotiations of the TPP, the Trans-Pacific Partnership, by building on the agreement with Korea and the principles in U.S. law, particularly the provision of 12 years of regulatory data protection for biologics.

Two, support efforts of the U.S. Government to secure full implementation of all international obligations under multilateral regional and bilateral trade agreements.

And three, support the IP attaché's program of the USPTO and other capacity building programs.

Effective patent enforcement is absolutely critical for growth in exports of our medicines. A country such as China, with weak patent enforcement, illustrates the problems encountered by our industry. In China, the enforcement of court orders is not automatic and damages are simply inadequate. Many countries permit the grant of compulsory licenses that allow others to exploit a patented invention without the permission of the patent owner. Compulsory licenses may be appropriate in extraordinary situations to meet legitimate needs of the public; however, competitors in many countries want to use them to obtain U.S. technology without having to make the costly and risky investment needed to develop it.

In many countries significant delays in granting patents create business uncertainty and, even worse, allow copiers to free ride and enter the market with impunity. PhRMA's members can wait an average of 8 years for a final patent rejection in Chile and 10 to 13 years in Brazil. To make matters worse, these countries do not extend the terms of their patents to compensate for these delays, nor for regulatory approval delays, as we do in the U.S.

As our statement for the record sets out, although PhRMA members are now able to get onto a playing field of patent protection, that field is far from level. Unfortunately, it is not just a game. The level playing field is critical to the future sustainability of U.S. innovation, innovative businesses, jobs, and exports.

We greatly appreciate, therefore, your interest in obtaining more information about the level of IP protection worldwide and we would be pleased to provide additional information. Thank you again.

[The prepared statement of Mr. Waldron follows:]

Statement of

Roy F. Waldron
Senior Vice President, Associate General Counsel
& Chief Intellectual Property Counsel
Pfizer, Inc

on behalf of

Pharmaceutical Research and Manufacturers of America

before the

SUBCOMMITTEE ON INTELLECTUAL PROPERTY, COMPETITION,
AND THE INTERNET
COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES

on

INTERNATIONAL PATENT ISSUES: PROMOTING A LEVEL PLAYING FIELD FOR AMERICAN INDUSTRY ABROAD

April 26, 2012

Mr. Chairman and Members of the Subcommittee:

Thank you for this opportunity to appear today and to discuss patent laws and government policies and practices that skew the playing field applicable to the research-based pharmaceutical industry when it attempts to protect its innovative and life-saving products in other countries.

My name is Roy Waldron and I am the Chief Intellectual Property Counsel for Pfizer, Inc. As part of my responsibilities at Pfizer, I oversee the acquisition and enforcement of patents and trademarks worldwide. I am also Chairman of the Intellectual Property Task Force within the International division of the Pharmaceutical Research and Manufacturers of America (PhRMA). This Task Force has the responsibility for reviewing and responding to patent laws and government policies and practices in other countries for the association. It is in my capacity as Chairman of the Task Force that I appear before you today.

PhRMA represents the country's leading pharmaceutical research and biotechnology companies. Its members are devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. Consistent with the Congressional Budget Office's finding that the pharmaceutical sector is one of the nation's most research-intensive sectors, PhRMA members invested an estimated $49.5 billion in research and development in 2011.[1] Medicines developed by member companies have produced large improvements in health across a broad range of diseases, with the rapid growth of biological knowledge creating growing opportunities for continued profound advances against disease. In 2011, 3,240 medicines were in clinical trials or under review by the Food and Drug Administration (FDA) in the U.S., versus about 2,200 medicines in development in the rest of the world combined.[2]

U.S. biopharmaceutical research makes important economic contributions to U.S. gross domestic product, contributions likely to grow if the incentives and underpinnings for large-scale research and development (R&D) investment remain intact. According to a recent study by Battelle Technology Partnership Practice (Battelle), the U.S. biopharmaceutical sector supported a total of 4 million jobs in 2009, including more than 650,000 direct jobs.[3] Battelle also reports that the U.S. biopharmaceutical sector has a high multiplier effect – in 2009, each job in a biopharmaceutical research company supported almost five jobs across the economy, ranging from biopharmaceutical manufacturing jobs to construction and other building service jobs, to contract researchers and child care providers. The U.S. biopharmaceutical industry also exported about $46 billion in goods in 2011, making it the sixth largest U.S. exporting industry for the year.[4] Markets outside of the U.S. are fueling demand for innovative medicines due to their increasing economic growth and rising middle class. Although this creates substantial export opportunities for U.S. companies, there are substantial challenges in many of these countries that impede member companies' ability to grow exports and the high-wage, high-skill jobs that this

[1] Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey (Washington, DC: PhRMA 1981-2012).
[2] Adis R&D Insight Database, Wolters Kluwer Health (accessed February 10, 2012).
[3] Batelle Technology Partnership Practice, The U.S. Biopharmaceuticals Sector: Economic Contribution of the Nation (Columbus, OH: Batelle Memorial Institute, July 2011).
[4] *See* http://dataweb.usitc.gov/, accessed April 17, 2012 (query run of U.S. domestic exports classified by 4-digit NAIC code 3254).

demand generates. We applaud the Subcommittee's interest in promoting a level playing field and fostering U.S. global competitiveness.

I. Background and Summary of Testimony

Developing a new medicine takes between 10 and 15 years of work and costs, on average, more than $1 billion of investment in research and development.[5] Like innovators across the spectrum of American industries, pharmaceutical companies make the substantial R&D investments that yield new medicines in reliance on a legal regime that provides protection for any resulting intellectual property. PhRMA members rely on patents to protect their inventions and provide an opportunity to recover their research investments. But patents are particularly important to pharmaceutical innovation given the research-intensive nature of this sector and the substantial investment required to discover and develop products that meet FDA approval requirements.[6]

Although strong intellectual property protections are provided in the United States, this is not true in many of the developing countries where the greatest growth potential for innovative medicines developed by the U.S. biopharmaceutical industry is expected to occur over the next few years. In many of these countries, local biopharmaceutical companies are owned by or connected to the government and/or supported by the government's industrial policies. The main competitive edge of the U.S. biopharmaceutical industry relative to these local businesses is the innovative nature of their products. While developing and testing innovative medicines requires large investments and a high degree of risk, copying the final product can often occur with relatively small effort or risk in a short period of time. The competitive advantage of the U.S. biopharmaceutical industry and its corresponding ability to increase exports and associated jobs is, therefore, dependent on legal principles and mechanisms which recognize and effectively enforce patents and other forms of intellectual property associated with new medicines. Establishing these principles and mechanisms is often strongly resisted by both local interests and government policies that favor national business interests.

Each year, PhRMA includes a comprehensive list of the barriers faced by member companies in a submission to the U.S. Trade Representative (USTR) as part of the annual "Special 301" review process.[7] Rather than recite this list (PhRMA submits comments on more than 40 countries), we will summarize the major categories of barriers that PhRMA members face with respect to patent systems abroad and cite some of the most significant examples of each. The key categories of barriers that PhRMA members face are:

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[5] JA DiMasi, and HG Grabowski. "The Cost of Biopharmaceutical R&D: Is Biotech Different?" Managerial and Decision Economics no. 28(2007): 469-79; PhRMA. "Drug Discovery and Development: Understanding the R&D Process." (Washington, DC: 2007).

[6] Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 Journal of Int'l Economic Law 849-60 (2002). Without patent protection, potential investors would see little prospect of a sufficient return on investment to offset the accompanying financial risk. Barfield, Claude, and Calfee, John. Biotechnology and the Patent System: Balancing Innovation and Property Rights. AEI Press, 2007. It has been estimated that without patent protection, 65% of pharmaceutical products would never have been brought to market, while the average across all other industries was a mere 8%. Edwin Mansfield, *Patents and Innovation: An Empirical Study*, Management Science (Feb. 1986) at 173-181.

[7] PhRMA's 2012 "Special 301" Submission is available on the "Regulations" website of the U.S. Government at http://www.regulations.gov/#!documentDetail;D=USTR-2011-0021-0010.

- Lack of effective patent enforcement, which includes challenges to obtaining injunctions and damages in patent cases, preventing inappropriate compulsory licenses, and ensuring governments honor patents and regulatory data protection periods before generic products are approved and launched;

- Administrative hurdles in the patent granting process and other administrative procedures, which include delays in examination and grant, use of non-patent related criteria, pre-grant oppositions, additional regulatory procedures and resultant diminution of the effective patent term; and

- Unclear and arbitrary requirements for patent grant, which include expansive utility data support requirements that represent additional standards or hurdles.

Some of these barriers appear to be inconsistent with obligations of governments under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the North American Free Trade Agreement (NAFTA), or other trade and commercial agreements. Conversely, innovators in other countries receive the benefits of an effective patent system in the United States that meets these international obligations. To improve the competitive environment abroad and move towards a more level playing field, we would greatly appreciate efforts by Members of this Committee to:

- ensure that the U.S. Government articulates and pursues strong intellectual property standards in Free Trade Agreements (FTAs) (including the ongoing negotiations of the Trans-Pacific Partnership) by building on the obligations in the recent Agreement with Korea and the principles found in U.S. law (*i.e.*, 12 years of regulatory data protection for biologics);

- support ongoing efforts of the U.S. Government to secure full implementation of existing and future international obligations under multilateral, regional and bilateral trade agreements; and

- support the system of the IP Attachés administered by the U.S. Patent and Trademark Office and various forms of technical assistance and capacity building programs sponsored by the U.S. Government and other institutions.

II. Enforcement

Patent enforcement is a basic element needed to provide conditions that support successful growth in exports of innovative medicines. Some of the obstacles in enforcement systems are illustrated here.

A. Obtaining Injunctions and Damages – China

Many countries have at least one barrier to patent enforcement in their legal regime, and these barriers differ from country to country. China, however, seems to exhibit many of the common barriers – inadequate damages, lack of timely relief, duplicative procedures, time-consuming formalities and ineffective injunctions.

Overall, the level of damages available to a plaintiff is insufficient to deter infringement or make a plaintiff whole. For example, the Patent Law in China sets out four possible methods for calculation of damages in a patent case, but in practice the court in virtually every case reverts to the fourth method, which has a cap of RMB 1 million (roughly $156,000), an amount that often does not compensate the patent owner and does not deter potential infringers.[8] Moreover, other methods for deterring infringement are not available. For example, there is no mechanism for enhancement of the damages in the case of willful infringement and attorneys' fees are not available as a practical matter.

Preliminary injunctions are theoretically available from courts,[9] but they are rarely granted. Judges are reluctant to issue them because they do not have published or precedential standards governing the "irreparable harm" to guide them. Judges are also hesitant to issue preliminary injunctions in cases involving complicated technologies. Preliminary injunctions are more important in China than in some other jurisdictions because money damages are not adequate to compensate the patent owner, as discussed above.

Enforcement of court orders, whether damages or injunctions, is not automatic in China; if the losing party fails to comply, the winning party must apply separately to an enforcement tribunal to compel enforcement. The enforcement tribunals, in turn, have considerable discretion with respect to whether, and how firmly, to enforce an order. While in theory an individual or responsible party (of an enterprise) can be fined or jailed for violating a court order, the fine is trivial, and a jail sentence is rarely imposed.

There are Local Patent Bureaus in China that have the authority to issue an "administrative" injunction against an infringer in their jurisdiction.[10] These Bureaus, however, have no authority to impose sanctions on infringers who do not comply with their injunctions, and patent owners must apply to a court in a separate action to enforce these orders. Furthermore, the local intellectual property authority is also limited to injunctive remedies; it cannot adjudicate damages. In any case, local intellectual property authorities are hesitant to adjudicate patent infringement complaints, at least where the matter is complex, because they lack expertise and resources for these cases. Thus, patent owners are both unable to obtain injunctive relief in a timely manner or obtain reasonable damages during or after these delays.

B. Compulsory Licensing

Many countries have provisions that permit government authorities to issue patent licenses to other entities to exploit the patented invention without the permission of the patent owner under specific circumstances. Such action is usually referred to as a compulsory license although there is no internationally accepted definition for that term.

Compulsory licenses can be granted in extraordinary situations of extreme urgency or other national emergency to meet the legitimate needs of the public. Often, however, compulsory licenses may be used by competitors as a means to obtain authorization to use or transfer

[8] Patent Law of the People's Republic of China, Art. 65, available at http://www.wipo.int/wipolex/en/text.jsp?file_id=178664.
[9] *Id.* at Art. 66.
[10] *Id.* at Arts. 3, 60, and 64.

technology developed by others without having to pay the costs associated with developing and testing the product. These copiers want to obtain a free ride or use the technology at a much reduced cost. Also, compulsory licenses are inappropriately viewed by some governments as part of their industrial policy to establish domestic production or their health policy to reduce government expenditures for medicines.

1. Thailand

The Government of Thailand granted compulsory licenses in 2006 to patents covering three major products: two protease inhibitors and one product for preventing strokes and heart attacks.[11] Unofficially, government officials acknowledged that part of the motivation for granting these three compulsory licenses was because the budget could not cover the cost of reimbursing these innovative products. Royalties were set at 0.5 percent of "sales" for products with high volume sales, and up to 2.0 percent of sales for products with lower volume sales.[12] It should be noted that each of the three products were manufactured or acquired by an entity owned and controlled by the Thai Government. The licenses for patents covering two products were renewed in 2011 and the other patent expired.

2. India

The Indian Controller General of Patents granted the first compulsory license under the amended Patents Act in March of this year.[13] The compulsory license related to a patent covering a product to treat liver and kidney cancer. The patent owner had only a limited opportunity to market its product given that a local company (Cipla) was successfully marketing a copy of the patent owner's product. The patent owner initiated an infringement action against Cipla, a case which is still pending.[14]

A second local company (Natco) applied for a compulsory license on the basis that the patent owner was not meeting the demands of the public at reasonable prices and that the patent owner was not manufacturing the patented product in India.[15] The Controller agreed that the patent owner was required to manufacture the patented product in India despite the prohibition in TRIPS Article 27.1 to the contrary. In addition, the Controller decided that the patent owner had to supply the entire market in India even though Cipla's product remained in the market. The order granting the compulsory license provided for a royalty to the patent owner of six percent of net sales of the products produced under the license, but established price controls at levels far below even Cipla's price.[16]

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[11] The Ministry of Public Health and The National Health Security Office of Thailand. "Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand," February 2007.

[12] The Ministry of Public Health and The National Health Security Office of Thailand. "Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand," February 2007, p. 11.

[13] Compulsory License Application No. 1 of 2011. Granted March 9, 2012 by P.H. Kurian.

[14] *Bayer Corporation Anr. V. Cipla Ltd.* C.S. (O.S.) No. 523 of 2010.

[15] The Compulsory License Application No. 1 of 2011 from M/S. Natco Pharma Ltd. in Patent No. 215758. Published Office Journal of the Patent Office, Issue No. 32/2011. August 12, 2011.

[16] Compulsory License Application No. 1 of 2011. Granted March 9, 2012 by P.H. Kurian.

C. Effective Enforcement Mechanisms before Generic Approvals

Many countries provide mechanisms in their regulatory approval process to provide for adjudication of patent infringement or validity claims before generic or biosimilar products are marketed. This opportunity to resolve issues early is helpful to patients and generic companies as well as the innovators. Regrettably, many countries have not established effective mechanisms to accomplish this objective.

1. Mexico

A Decree in 2003 was intended to "link" the regulatory regime for pharmaceutical products with the patent system. Unfortunately, the Decree is not being applied to a very important class of pharmaceutical patents – formulations. New formulations are often more effective and efficient than the original formulations and usually better respond to a patient's medical needs. For example, a new formulation may allow a patient to take one pill per month (delayed-release to enhance adherence), rather than one or more pills per day, and may have the same or improved therapeutic effect. Yet, these important inventions cannot benefit from the linkage system provided by the Decree.

Moreover, PhRMA and its members are concerned that health authorities in Mexico (*i.e.*, COFEPRIS) are increasingly approving the marketing of copies of patented products without the permission of the patent owner, despite the requirements of the Decree.

2. Chile

Chile has not implemented its FTA obligations. Specifically, Article 17.10.2 of the U.S.-Chile Free Trade Agreement requires Chile to implement an effective enforcement mechanism. To date, Chile has failed to establish a satisfactory mechanism to enable effective patent enforcement before marketing approval decisions are made and implemented and PhRMA's members believe that several copied products have received marketing approval despite being covered by a patent.

During 2011, the Chilean Government indicated to USTR and the innovative pharmaceutical industry its recognition of the need to enact new legislation aimed at establishing an effective patent enforcement mechanism that would bring Chile closer to compliance with its FTA obligations. Legislation is pending, but to the best of our knowledge has not yet been enacted.

D. Regulatory Data Protection

The development of test and other data to prove to regulatory authorities that pharmaceutical products are safe and effective requires significant investment (without any guarantees of success) over an extended period. To encourage the development of these data and subsequently the marketing of new pharmaceutical products, TRIPS Article 39.3 requires WTO Members to protect these data from disclosure and unfair commercial use.

It should be noted that although patents and regulatory data protection (sometimes referred to as "data exclusivity") may prevent others from copying a pharmaceutical product, patents and regulatory data protection are very different forms of protection with their own terms, and are

provided for very different reasons. Patents protect the new, useful, and non-obvious inventions. Regulatory data protection encourages the development of the data required to prove that a product is safe and effective, regardless of whether the product is covered by patents.

For products that are not eligible for patents (*e.g.*, products based on naturally occurring materials or compounds which had been known in the past), data protection is the only effective protection available. In countries where the availability of litigation to resolve patent disputes is more theoretical than real, data protection is also the only effective form of protection for pharmaceutical products.

Many countries do not provide effective data protection. Although regulatory data protection is required by the TRIPS Agreement, some countries do not have any effective protection for regulatory data, *e.g.*, India. We also have concerns about the regimes in other trading partners with whom we have FTAs. Several examples follow:

1. Chile

Supreme Decree 107 of 2010 provides a regime for the protection of data in Chile, but there are still some significant problems with this regime. For example, data associated with proving the safety and efficacy of new uses, new formulations, and new dosage forms of known products, as well as data associated with new compositions containing known products, are not eligible for protection. In Chile, holders of the data must supply applications to obtain data protection; a formality not provided for in international agreements, which may erode the effectiveness of regulatory data protection.

2. Mexico

Mexico has a statute that provides, in essence, that the obligations related to regulatory data protection in the TRIPS Agreement and the NAFTA apply directly in Mexico. Mexico has not, however, enacted any other statutes or promulgated regulations to implement their obligations related to regulatory data protection. As a consequence, there is no Mexican regulatory official specifically authorized to protect data and there is no guidance on important attributes of data protection such as the term of protection. Consequently, adequate steps have not been taken by Mexico to protect these data effectively.

3. China

The Implementation Regulation of the Drug Administration Law and the Drug Registration Regulation establish a six-year period of protection for test data of products containing a new chemical ingredient against unfair commercial use. The State Food and Drug Administration (SFDA) is responsible for upholding this Law and Regulation. Unfortunately, the current law is ambiguous as to how data protection should be implemented. For example, particular key concepts such as "new chemical ingredient" and "unfair commercial use" are undefined, resulting in substantial business uncertainty for companies.

SFDA interprets the Law and Regulation to allow it to deny data protection for data associated with obtaining marketing approval for pharmaceutical products first marketed outside of China.

As a practical matter, this interpretation results in the elimination of protection for all but Chinese entities. Moreover, the SFDA allows companies to market copies based on the approvals of an originator's product in another country or published information about the original product. This reliance constitutes not only unfair commercial use, but also typically provides insufficient proof, as a scientific matter, of the safety and efficacy of the copy product.

III. Patent Granting Process and Other Administrative Procedures

Businesses need reasonable assurance that a patent meets the requirements of the law and that the patent will be granted in a timely manner. Some countries are not able to provide these assurances, as the following examples illustrate.

A. Delays in Examination and Grant

PhRMA members face significant delays in obtaining an initial examination and the grant of their applications in a number of countries. As a reference point, the U.S. Patent and Trademark Office reports that in March 2012, the average time between filing an application and the first office action on the merits for applications in all fields of technology was 23.3 months. The average total pendency was 34 months.[17] At the moment, the Office estimates that the time until the first office action on applications related to therapeutic compounds will range from 15 to 19 months.[18] Unfortunately, we do not have comprehensive data at hand for other countries, but we have substantial anecdotal evidence, including the following examples:

- For many years, applicants for pharmaceutical patents in Chile have had to wait an average of eight years to obtain final action on their applications by the Chilean patent office. While the National Institute of Industrial Property in Chile instituted a number of procedural reforms to reduce the patent pendency periods, PhRMA members have not yet seen any substantial reduction in the time required to obtain definitive decisions on their patent applications.

- We do not have official statistics from Brazil, but patent counsel in Brazil report that the Brazilian patent office is only now examining applications in the pharmaceutical field filed during the period from 1999 to 2002 – the newest is a decade ago. We are not the only field of technology with delays; we understand that the Brazilian patent office is now examining applications for agrichemicals filed between 2001 and 2003 and applications for other chemicals from 2001 to 2004.

- The lack of qualified examiners may cause significant delays in examination. For example, the last annual report of the Indian Controller General for Patents, Designs and Trademarks states that his office received 34,287 patent applications in all fields of technology, but only examined 6,069 applications in their 2009-2010 year. This low ratio of examinations relative to applications was attributed to several factors, the most important of which was that only 80 patent examiners were available during that period.

[17] Available at http://www.uspto.gov/dashboards/patents/main.dashxml (last visited April 17, 2012).
[18] This estimate is for applications designated in Class 424, entitled "Drugs, bio-affecting and body treating compositions."

More recently, we received reports that there are still only about 200 patent examiners at the Indian Office of the Controller-General but there were 83,686 applications to be examined as of March 2011. Unless some extraordinary steps are taken, it will be years before this backlog of applications will be examined; and new applications will be submitted during those years.

B. Use of Non-patent Related Criteria – Brazil

An amendment in 1999 to the Brazilian Industrial Property Law[19] authorized the agency that regulates pharmaceutical products (ANVISA) to review all patent applications for pharmaceutical products and/or processes. This review is in addition to the examination conducted by Brazil's patent office, the National Industrial Property Office (INPI). This review creates delays in obtaining patents in the pharmaceutical field that do not exist for other fields of technology. Moreover, examiners from ANVISA apply criteria that are different from the criteria permitted by TRIPS Article 27. Often this results in different decisions on patentability or additional delays in the patent process, which does not occur for applications in other fields of technology. At times, the delays and differences in decisions were so severe that it appeared that INPI was not granting patents on inventions in the pharmaceutical field.

This use of non-patent related criteria as instituted by the Government of Brazil is inconsistent with TRIPS Article 27.1, which prohibits discrimination in procedures to grant patents based on the field of technology of the invention. For this and other reasons, Brazil's Federal Attorney General recommended in 2009 that the role of ANVISA in the patent examination process be limited. An inter-ministerial group was supposed to review the role of ANVISA and was supposed to report its findings in January of this year, but the group has not yet released a report.

C. Pre-grant Oppositions

In most countries, applications for patents are examined *ex parte* and published at some point before they are granted. Some countries, however, allow interested parties to "oppose" the grant of the patent after publication but before the date established for the grant of the patent. These countries often set up elaborate *inter partes* proceedings to determine patentability. Of course, these procedures take additional time and resources. Given that the term of patent protection is measured from the date of first filing, these delays erode the effective life of the patent.

If not properly policed, these pre-grant oppositions are opportunities for abuse. Interested parties can effectively delay patent grants for extended periods, often for little cost and without impunity. These delays can eliminate the ability of the inventor to initiate infringement actions to stop copiers already in the market. If the patent is granted after the opposition, the interested party may be able to re-package allegations from the pre-grant oppositions in subsequent infringement actions. This adds burdens on all concerned without adding any significant benefits.

Post-grant proceedings to invalidate patents do not suffer from the same troubles as pre-grant proceedings and are a far superior method for patent offices to determine the patentability more quickly and less expensively than litigation. Nevertheless, some countries still cling to pre-grant

[19] The amendment added a new Article 229-C to the Industrial Property Law No. 9,279 (1996).

opposition procedures. For example, India provides for a pre-grant procedure in Article 25(1) of the Indian Patents Act. Some member companies have reported delays in concluding these procedures for individual applications in several countries, including India, Colombia and Ecuador. Unlike the United States, these countries do not provide for extension of patent terms to compensate for delays in patent processing.

D. Regulatory Procedures and Effective Patent Term

Most countries require that some inventions be reviewed by regulatory authorities before they can be marketed. For example, in the United States, the Food and Drug Administration must review and approve pharmaceutical products before they can be marketed to ensure that they are safe and effective. The time period associated with the regulatory process for marketing approvals can be lengthy. These periods can erode the effective term of the patent and reduce the usefulness of the patent significantly.

Most countries have legitimate safety and efficacy requirements which can cause delays in the ability to obtain approval to market a product. But, there can be issues beyond the determination of safety and effectiveness of the product *per se,* and these can be problematic.

Turkey is a prime example of a country with problematic regulatory procedures. Its legislation requires the Turkish Ministry of Health to assess and authorize the registration of medicinal products within 210 days. Surveys by the Association of Research-Based Pharmaceutical Companies (AIFD) indicate that the regulatory approval period exceeded 850 days in 2011.[20]

The Ministry's revisions to the Registration Regulation have compounded these delays.[21] Effective March 1, 2010, a Good Manufacturing Practices (GMP) certificate that is issued by the Ministry must be submitted with each application to register a medicinal product for each of the facilities at which the product is manufactured. The GMP certificate can only be issued by the Ministry following an on-site inspection by Ministry staff, or by the competent authority of a country that recognizes the GMP certificates issued by the Ministry.

AIFD estimates that approximately 300 innovative products manufactured outside Turkey, including anti-infectives, antipsychotics, vaccines, as well as cardiovascular, diabetes and oncology drugs, are currently awaiting registration by the Ministry. Further, the Ministry has thus far received approximately 550 applications to conduct GMP inspections, requiring inspections at almost 330 overseas sites.[22] The Ministry does not have an adequate number of staff to complete these GMP inspections in a timely manner and there are significant barriers to acceptance of the GMP certificates issued by other countries. The effective term of protection of the patent is eroded by such periods of regulatory approvals.

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[20] AIFD Situation Assessment Survey of CTD Applications, June 2011.
[21] Regulation to Amend the Registration Regulation of Medicinal Products for Human Use, Official Gazette No. 27208 (Apr. 22, 2009) (Amended Registration Regulation); MOH, *Important Announcement Regarding GMP Certificates*, (Dec. 31, 2009) (establishing an implementation date for the GMP certification requirement).
[22] AIFD GMP Inspections Survey, September 2011.

E. Lack of Safeguards

We believe that officials of the various patent offices should grant patents in a timely manner and officials of regulatory agencies should provide prompt review and approval of products to prevent the foreshortening of the period of time when the patented invention is protected and used. We understand, however, that the prompt grant of patents and marketing approvals is not always possible. When they are not possible, we believe that it is appropriate and equitable for countries to restore the term of the patents to compensate for delays in marketing due to marketing approval procedures and to adjust the term of patents to compensate for delays in granting patents that were not due to the patent owner, as is the case in the United States.

Most countries refuse to provide either of these safeguards. For example, Members of the Andean Community are expressly forbidden from providing for extension of the patent term to compensate for delays in processing their patent applications covering pharmaceutical products, by Article 1(d) of Decision 689 that amends Decision 486. Members of the Andean Community may extend the terms of patents in other fields of technology. Canada does not provide for restoration of a patent term due to delays in obtaining marketing approval or patent grant.

IV. Requirements for Patent Grant

Every country with a patent system requires that patents may only be granted for inventions that are new, useful, and non-obvious. In addition, countries require that the invention be disclosed in a manner that enables a person, skilled in the field of technology to which the invention pertains, to carry out the invention. This latter requirement is often called the "enablement" or "sufficiency" requirement. The "utility" requirement demands the invention be useful in that it complies with threshold questions of what is patent-eligible subject matter. Under the TRIPS Agreement, WTO Members are not permitted to add further substantive requirements for patentability.

Countries have different definitions of these four requirements and different rules for determining whether these requirements are fulfilled. Sometimes, these requirements and rules preclude patentability of inventions that would be considered by most countries to be worthy of a patent. We believe that the requirements in these countries are inappropriate and unfair.

A. Patent Eligibility Requirement – Canada

Canadian courts have recently defined one of the patent eligibility requirements, which is often referred to as its "utility" requirement, in a manner that adds a barrier to grant and burdens patent owners. For example, applicants for patents often honestly assert and believe at the time of filing their applications that their inventions have multiple uses. After experience with the invention, they may find that some of the asserted uses were valid, but that others were not. In the United States, the patent would still be valid if any of the assertions were accurate. In Canada, the applicant may be required to demonstrate that all assertions are accurate or the patent will be held invalid because the "promise of the invention" was not met. It makes little sense that a patent should be invalidated when one or more assertions of utility might not have been successful but other life-saving uses that were asserted in the patent application are established

by the inventor. We believe that this practice is unjustifiable in light of the realities of the long, difficult and clinically intense development process for pharmaceutical products.

In Canada, general assertions of utility (*e.g.*, useful as a medicine) do not have to be accompanied by evidence of utility, whereas specific assertions of utility (*e.g.*, treats rheumatoid arthritis) must be accompanied by such evidence. In short, an applicant is penalized for trying to be more precise. This penalty runs counter to the timely disclosure of technology, one of the goals of the patent system. These and other different standards place unreasonable burdens on applicants without any apparent social value.

B. Additional Standards – India

Section 3(d) of the Indian Patents Act, 1970, as amended, requires that applicants who claim certain chemical compounds, which are important in the pharmaceutical industry and based on known substances (*e.g.*, different salts, esters, ethers, polymorphs, and other derivatives), show that these compounds have significantly different properties than the known substances. Many inventions involving known substances, however, require substantial resources to develop and test, and represent significant advances for patients – and in fact may turn what may be merely compounds of interest into a therapeutic treatment for disease. This requirement blocks patents to these valuable inventions and discriminates against them. This requirement is in addition to the four requirements set forth in the TRIPS Agreement and is specific to the pharmaceutical field of technology. As a result, it is inconsistent with India's obligations under the TRIPS Agreement.

V. Conclusion

Robust intellectual property protections in both the U.S. and around the world are critical to advance U.S. competitiveness, grow knowledge based jobs in-country, increase exports, and ensure that patients have access to innovative medicines. Few industries provide more high-quality, high-paying, and high-productivity jobs in the U.S. than the biopharmaceutical sector. It is vital for the biopharmaceutical sector and the patients they serve that governments comply with international obligations to protect and enforce IP rights, including patents, trademarks, and regulatory data protection.

Today, PhRMA members can at least legally get on the "playing field" of patent protection, which is a vast improvement over the situation 30 years ago. But, the problems discussed illustrate that they are still not playing on a level field in many cases. In some countries, our member companies cannot obtain patents or obtain them in a timely manner. If PhRMA members are able to obtain patents, they face significant problems enforcing them in some countries – which is where the true value lies.

PhRMA and its member companies are working actively to resolve these problems and appreciate the assistance and support of Office of the U.S. Trade Representative, the Departments of State and Commerce, as well as others.

Finally, we appreciate your interest in obtaining more information on level of protection worldwide and would be pleased to provide additional explanations or information. Thank you.

Mr. GOODLATTE. Thank you, Dr. Waldron. Mr. Israel, welcome.

TESTIMONY OF CHRIS ISRAEL, PARTNER, AMERICAN CONTINENTAL GROUP (FORMER U.S. COORDINATOR FOR INTERNATIONAL INTELLECTUAL PROPERTY ENFORCEMENT)

Mr. ISRAEL. Thank you. Chairman Goodlatte, Ranking Member Watt, and Members of the Committee, I truly appreciate the opportunity to appear before you to discuss the promotion and protection of American intellectual property and specifically to examine challenges and barriers presented to American companies when they seek patent protection in key global markets.

From May 2005 to March 2008, I had the privilege of serving as the U.S. Coordinator for International Intellectual Property Enforcement. We were tasked by Congress and the President to coordinate and leverage the resources of the U.S. Federal Government to protect American IP at home and abroad. Mr. Chairman, during my experience in this position, it became clear to me that it was and remains critical for the U.S. Government to actively seek every opportunity to support IP-intensive U.S. companies competing globally in their compelling economic interests. It is clear that adequate and effective global patent protection is essential to U.S. competitiveness, and I would argue that there are several key reasons for this.

First, as you noted in your opening statements, Mr. Chairman, and directly related to the work of this Committee is the passage of the Leahy-Smith America Invents Act. The AIA represents a major achievement in strengthening and modernizing U.S. patent law and making it the global standard for quality and efficiency. While the USPTO continues to implement the AIA in a methodical and thoughtful way, many of our biggest competitors are going either advertently or inadvertently in the opposite direction. This disconnect, as was noted by Ranking Member Watt, with the U.S. setting the global standard while other countries seek competitive advantage by racing to the bottom, is certainly not a new competitive dynamic for the United States but seeing it play out in terms of global patent policy is something policymakers need to be aware of and prepared to address.

Second, exacerbating this problem is the fact that we are seeing a dramatic increase in international patent filing in the countries that often expose U.S. companies to poor patent protection. The growth in patent applications in China, India, and Brazil from 2006 to 2010 average 7 percent a year, while the growth in patent applications in the United States, the EU, and Japan over the same period average 0.7 percent.

Third, and perhaps most importantly, the challenges and threats to global patent protection affect our most competitive and innovative companies and industries. As was reported in the Obama administration report that Ranking Member Watt noted in his opening comments, the 26 patent intensive industries in the United States support 3.9 million very well-paying jobs. Not surprisingly, our U.S. patent-intensive industries also drive U.S. exports. Our innovative products lead the world and span multiple categories, including health care, advanced manufacturing, chemicals, energy, transportation, software, information technology, and others. These

are areas where the U.S. must seek to increase its competitive advantage through innovation and global commercialization. This can only be accomplished when coupled with a policy approach that promotes strong patent protection.

Mr. Chairman, while my written testimony provides detailed examples of the many ways our trading partners have undercut American innovation through overt and less obvious practices, I would like to quickly bring a few of these examples to the attention of the Committee.

Some countries explicitly restrict the patentability of inventions for a number of unrelated factors purely for competitive reasons. For example, India excludes software patents as a whole, except when combined with novel hardware. In the context of breakthrough U.S. innovations in clean technologies, countries such as China, India, Bolivia, Venezuela, and others have pushed for a range of, quote, flexibilities in global patent rules under the false claim that patent protections hinder the flow of important energy-related technologies. Additionally, countries such as Chile, Brazil, India, Russia, Argentina and others have continuously avoided requirements in the TRIPS Agreement to provide exclusivity for proprietary data that is required in order to grant marketing approval to pharmaceutical agrichemical and biotechnology products.

Also a major concern of many U.S. innovators is the threat of countries issuing compulsory licenses for their products, essentially breaking the patent and allowing their competitors to manufacture and market a product in that country. India recently issued a compulsory license for a patent that was held by a U.S. subsidiary of Bayer.

The Chinese Government even subsidizes the development of domestic technologies by providing direct financial support for Chinese companies to file foreign patent applications. China also discriminates against foreign competitors by limiting the ability of non-Chinese IP owners to access the Chinese market.

Mr. Chairman, this Committee has raised an important issue that impacts countless U.S. businesses of all sizes and is at the core of our overall global competitiveness. I truly appreciate the opportunity to participate in this hearing and look forward for any chance to support the work of the Subcommittee and the Committee in the future.

[The prepared statement of Mr. Israel follows:]

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Statement of

Chris Israel
Partner
American Continental Group
(Former U.S. Coordinator for International Intellectual Property Enforcement)

before the

HOUSE COMMITTEE ON THE JUDICIARY

SUBCOMMITTEE ON INTELLECTUAL PROPERTY, COMPETITION AND THE INTERNET

on

"INTERNATIONAL PATENT ISSUES: PROMOTING A LEVEL PLAYING FIELD FOR AMERICAN INDUSTRY ABROAD"

Thursday, April 26, 2012

Chairman Goodlatte, Ranking Member Watt and Members of the Subcommittee, I appreciate the opportunity to appear before you to discuss the promotion and protection of American intellectual property overseas and specifically, to examine challenges and barriers presented to American companies when they seek patent protection in key markets.

(Please note that this statement reflects my own personal views and is not given on behalf of my firm or any of its clients.)

I. The Increasing Importance of International Patent Issues

From May 2005 to March 2008 I had the privilege of serving as the U.S. Coordinator for International Intellectual Property (IP) Enforcement. We were tasked by Congress and the President to coordinate and leverage the resources of the U.S. Government to protect American IP at home and abroad. This effort included a number of steps designed to recognize the importance of international patent enforcement matters. We focused on three key elements: actively engaging our trading partners, promoting patent protection through trade policy and supporting U.S. businesses.

First, it was our experience that the direct and high-level engagement of the U.S. Government is critical to confronting challenges to the protection of innovation and IP globally. We led multiple interagency IP policy delegations to countries including China, India, Russia, and Mexico. These discussions underscored key concerns of the U.S. Government and focused on specific deficiencies that harmed U.S. companies as they sought patent protection. We also engaged extensively with partners such as the EU and Japan to coordinate efforts to promote global patent protection and launched efforts such as the U.S.-EU IP Working Group to institutionalize this collaboration. We coupled these efforts with engagement at the highest level, including inclusion of IP enforcement for the within the work plan of the G8 and the elevation of patent policy within key bilateral fora such as the Joint Committee on Commerce and Trade (JCCT) with China and the U.S.-China Strategic Economic Dialogue.

And, in an action that would become the touchstone for dialogue between the U.S. and China, former U.S. Ambassador Clark T. Randt, Jr. established the Annual Ambassador's IP Roundtable in Beijing. This event often included Cabinet-level participation from the U.S. and the presence of the Chinese Vice Premier.

Next, we established a framework that promoted broad principles of patent protection within our overall trade policy and trade agreements. The U.S. certainly has a tremendous amount of leverage as countries seek to expand their own access to the U.S. market, and 17 agreements negotiated with countries such as Australia, Jordan, Singapore, Peru, Korea, Chile, Panama, Colombia and CAFTA-DR all contain strong IP provisions including provisions that protect regulatory data, require patent linkage and make patent term restoration available to compensate for unwarranted delays in the marketing approval process. Today, ongoing negotiations to establish an ambitious Trans-Pacific Partnership (TPP) provide an important opportunity to continue this progression towards strong, effective global patent protection for U.S. businesses. TPP is being negotiated as if Trade Promotion Authority (TPA) were in place (which it unfortunately is not), and under this framework we should look to the Trade Act of 2002 which provided TPA until 2007 and which requires that agreements be modeled on existing U.S. law. This would argue for provisions such as a 5 year term of data exclusivity for small molecule drugs and 12 years of data exclusivity for biological drugs.

As part of our efforts, we also directly engaged a number of key trading partners to provide capacity-building programs designed to address weaknesses within their patent systems or enforcement procedures that negatively impact U.S. businesses. For example, a case referral mechanism was established allowing the U.S. Government to refer problems of patent enforcement directly to Chinese officials, the United States Patent and Trademark Office (USPTO) conducted numerous technical exchanges with major patent offices to increase their capacity and quality, a Patent Prosecution Highway was established to allow information sharing between certain patent offices, and experts from the Department of Justice helped train Indian judges to more effectively adjudicate IP infringement cases.

Finally, it was (and remains) critical for the U.S. Government to provide guidance and support for IP-intensive U.S. companies competing globally. In an environment of limited resources and competing priorities, there are smart and effective ways to assist U.S. companies by providing information and best-practices and also through direct intervention. In my opinion, the U.S. Government should have no reluctance to provide whatever support it can to assure U.S. companies compete on a level playing field as they seek to patent and commercialize their products in key markets. We will always

adhere to market-based principles and free trade, but the U.S. Government should not shy away from providing support and direct engagement when necessary. Here are some examples:

- The USPTO's Overseas Intellectual Property Rights Attaché program launched in 2006 has placed IP experts in seven countries including China, India, Brazil, India, Egypt, Thailand and Mexico. This program provides invaluable support to U.S. companies which have questions about important markets and/or face specific problems. U.S. IP attaches have engaged with hundreds of companies and interact daily with foreign IP officials to seek improvements and to advocate on behalf of U.S. companies.

- Nearly 20 Country IPR Toolkits were designed to provide U.S. companies (particularly small and medium-sized enterprises) expert guidance on patent policies and enforcement procedures in key global markets.

- In 2008, Secretary of Homeland Security Michael Chertoff and Secretary of Commerce Carlos Gutierrez joined with multiple federal agencies and business leaders to open an expansive Intellectual Property Rights Coordination Center. The IPR Center has become a critical resource for U.S. companies to engage directly with policy and enforcement agencies to address specific matters that impact their ability to protect their intellectual property.

- Using high-level bilateral engagement to pursue action on behalf of U.S. companies is a critically important role for the U.S. Government. In countries where decisions regarding issues such as patent exclusions, compulsory licenses and patentability are being made for political reasons it is appropriate and important for the U.S. Government to voice its concern and seek to counteract this activity. These practices often violate the letter and spirit of international trade law and our trade agreements and they will proliferate if not addressed in a serious manner. The U.S. Government should also seek out like-minded countries and remain very engaged and active within the World Trade Organization and the World Intellectual Property Organization, where efforts are underway to roll back existing patent protections.

II. Adequate and Effective Global Patent Protection is a Matter of U.S. Competitiveness

As efforts such as those outlined above have developed and grown, their importance has also increased dramatically. I would argue there are several key reasons for this.

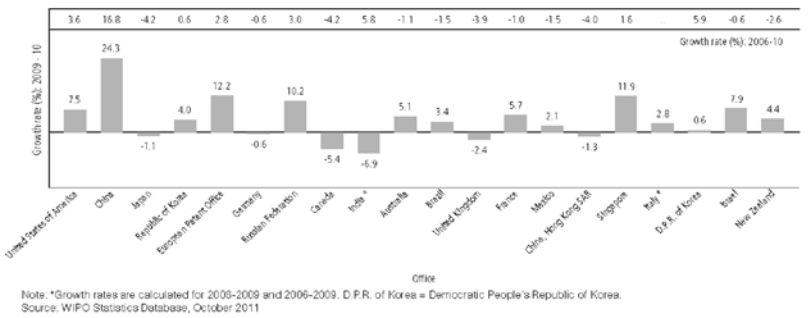
First and directly related to the work of this Committee, is the passage of the Leahy-Smith America Invents Act (AIA). The AIA represents a major achievement in strengthening and modernizing U.S. patent law and making it the global standard for quality and efficiency. Congress, working with the U.S. patent community and the USPTO, has made a number of critical improvements to our patent system that will unleash American innovation by improving patent quality, supporting U.S. manufacturing, providing more certainty for patent owners, and, very importantly, ensuring adequate funding for the USPTO. And under the leadership of USPTO Director Kappos we are witnessing the methodical and thoughtful implementation of the AIA. Unfortunately, many of our biggest competitors are going, either advertently or inadvertently, in the exact opposite direction. The patent backlog in Brazil is as long as 10 years, and when a patent is finally granted, Brazil provides wide exemptions for patent infringement that can make the patent nearly impossible to enforce. India's regional patent system can create tremendous problems with U.S. companies reporting that they have filed in separate regional patent offices and gotten opposite results. Thailand's regulatory authorities fail to even check if a valid patent exists when providing marketing approval for generic pharmaceuticals still under patent. And China is aggressively using its patent system to promote "indigenous innovation" and undercut U.S. innovators.

This disconnect, with the U.S. setting the global standard while other countries seek competitive advantages by racing to the bottom, is certainly not a new competitive dynamic for the U.S., but seeing it play out in terms of global patent policy is something policy makers need to be aware of and prepared to address.

Second, exacerbating this problem is the fact that we are seeing a dramatic increase in international patent filing, meaning that U.S. companies' exposure to an uneven playing field in terms of patent protection is growing exponentially. As depicted by the following chart from WIPO, the growth in patent applications in China, India and

Brazil from 2006-2010 was 7% a year. While the growth in patent applications in the U.S., EU and Japan over the same period was 0.7%. So, as the annual growth in applications to patent offices in the three historically largest offices has essentially leveled off in recent years, it is growing significantly in offices that have huge backlogs, major quality concerns and policies that undercut the overall value and enforceability of patents when granted.

Figure A.2.3.2. Growth rate of patent applications at the top 20 offices, 2010



Note: *Growth rates are calculated for 2008-2009 and 2006-2009. D.P.R. of Korea = Democratic People's Republic of Korea.
Source: WIPO Statistics Database, October 2011

Moreover, these countries are frequently seeking to export their policies through international fora such as the World Trade Organization, World Intellectual Property Organization, UN Framework Convention on Climate Change, World Health Organization and other bodies. For example, at the WIPO Standing Committee on Patents, Brazil has proposed that a manual be developed to instruct countries on how they can limit and weaken patent protections.

Third, and perhaps most importantly, the challenges and threats to global patent protection affect our most competitive and innovative companies and industries. As was reported by the Obama Administration in its March 2012 report "Intellectual Property and the U.S. Economy: Industries in Focus," the 26 patent-intensive industries in the U.S. support 3.9 million jobs. These patent-intensive jobs are nearly all in the manufacturing sector, so for those who seek to promote a competitive U.S. manufacturing base, the ability to ensure strong global patent protection must be a high priority. Furthermore, this same report finds that jobs in patent-intensive industries pay on average 42% higher than those in non patent-intensive industries.

Not surprisingly, the U.S. patent-intensive industries also drive U.S. exports. Our innovative products lead the world and span multiple categories including health care, advanced manufacturing, chemicals, energy, transportation, software, information technology and others. These are areas where the U.S. must seek to increase its competitive advantage through innovation and global commercialization. This can only be accomplished when coupled with a policy approach that promotes strong patent protection.

Countries that undercut American innovation through overt practices such as compulsory licenses, patent exclusions, lack of data exclusivity, patent subsidies and others or through less obvious features such as lengthy application backlogs, weak judicial enforcement, pre-grant opposition or indigenous innovation policies are mounting a direct threat to U.S. competitiveness.

We should consider the ability of U.S. companies to gain effective global patent protection an issue of core American competitiveness in the same way we are attempting to improve our tax code, regulatory policy, education system, R&D portfolio and other elements critical to our economic growth.

III. Issues and Countries of Specific Concern

So, where does the rubber meet the road and what specific challenges do U.S. companies face internationally?

It is difficult to clearly articulate and categorize the myriad concerns facing U.S. companies, but in simple terms they can be seen in two broad areas: those that appear to be in direct violation of international agreements such as the WTO TRIPS Agreement and/or U.S. Free Trade Agreements, and those that are more process based and may not explicitly violate trading rules, but still undercut patent quality and strength of enforcement – we could call these "compliant non-compliance."

The first category of direct violations is long and the problems have remained largely unchanged for years.

Exclusions, Restrictions, or "Flexibilities" on Patentability: WTO members are required to make patents available in all fields of technology, but a number of countries restrict patentability on a number of unrelated factors purely for competitive reasons.

For example, China requires filing an invention "made in China" prior to filing in another patent office. This is tremendously problematic for foreign applicants in what is now the world's largest patent office. If applicants file first in China how does this affect their standing at the USPTO? This policy has nothing to do with the strength and quality of the patent process in China but is designed to force innovators to manufacture in China while likely putting their IP at risk.

India and Brazil do not allow patents for secondary claims for novel uses. This is particularly harmful for health care companies which often adjust and improve products to serve unique and underserved communities.

Provisions like these are all inconsistent with Article 27 of the TRIPS Agreement which stipulates that patents must be made available to "any inventions … in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."

Another glaring example of patent exclusion is the fact that India excludes software patents as a whole except when combined with novel hardware. This does allow U.S. software companies to seek a limited level of patent protection in the important Indian market, but even this came under pressure recently when India considered eliminating all forms of patent protection for software in 2010. The U.S. Government, with notable leadership from the USPTO's IP attaché program in India, filed comments with the Indian government and helped preserve the status quo, which is well below the standard of patent protection for software offered in the U.S. and the EU, but clearly better than the alternative proposed by India.

In the context of breakthrough U.S. innovations in clean technology, we have seen a major push from countries including China, India, Bolivia and Venezuela for a range in "flexibilities" in global patent rules under the false claim that patent protections hinder the flow of important energy-related technologies. This would include broad exceptions to patentability or possibly compulsory licensing ability for "essential" technologies. However, it has become exceedingly clear that proposals such as these are short-sighted attempts to expropriate U.S. innovation and they do not accurately capture the realities behind the flow of global innovation.

A study released by the Brookings Institution in November 2009 notes that, while, "research on the empirical effects of property rights on technology transfer, particularly to developing nations is murky … strong IPR protection is an important catalyst for encouraging innovation in developing countries, and actually helps promote the sharing of technology as consistent and predictable legislative processes protect foreign direct investment and further joint ventures and international collaboration."

Two additional reports also published in 2009 from the U.S. and the EU clearly conclude that intellectual property rights are neither a barrier to innovation, nor do they hinder the diffusion of clean energy technologies to emerging and developing economies. These reports, from the U.S. International Trade Commission (ITC) and the EU Directorate General for Trade (DG Trade) actually go further, and conclude, that, in the words of the ITC, "patents are facilitating, not stifling innovation."

The EU's report makes the case even more clearly and at length, "IPR protection is not the main barrier preventing the transfer of environmental technologies to developing countries. A large number of relevant technologies are not patented in low-income developing countries, and in emerging market economies a significant number is patented by local companies." It goes on to say that, "there is a serious risk that a broad use of compulsory licensing (or other measures weakening IP rights) would constitute a disincentive for companies engaged in that sector, which might reduce their investment in such technologies. This would clearly be detrimental in the long term."

Calls for weakening patent protections for clean technologies were specifically rejected during UNFCCC meetings in 2010, but a broad coalition of developing countries and anti-IP non-governmental organizations continues to pursue an active agenda to create an uneven playing field for U.S. clean tech innovators.

Data Exclusivity: Article 39.3 of the TRIPS Agreement provides for the protection of undisclosed data that is required in order to grant marketing approval to pharmaceutical, agrichemical or biotechnology products. This framework is important in order to protect the significant investment and IP that is required to support marketing authorization and demonstrate that products are safe and effective. This is an independent intellectual property right and while it should be linked to the underlying patent(s) which it supports, it is appropriately protected as it requires

significant additional scientific discovery, cost and time to demonstrate the safety and efficacy of complex new products.

An appropriate and enforceable period of data exclusivity ensures that innovators can effectively recover the massive investment necessary to create and market new products. It does nothing to prohibit generic manufacturers from entering the market, it merely requires that they do their own, independent tests to demonstrate that their product meets the safety and efficacy requirements of the regulatory agency.

The standard in U.S. law is 5 years of data exclusivity for small molecule medicines and 12 years for biological products. This sets the baseline for our existing Free Trade Agreements, and should be the model for any future U.S. trade agreements. However a number of countries such as Chile, Brazil, India, Russia, Argentina and others fail to provide effective protection for the proprietary data provided as part of the regulatory approval process in their country.

Compulsory Licensing: Of major concern to many U.S. innovators is the threat of countries issuing compulsory licenses for their products, essentially breaking the patent and allowing their competitors to manufacture and market a product in that country. This is a direct threat to the integrity and predictability of any patent system. If, often after up to 8-10 years, a valid patent can simply be brushed aside by a national government for reasons that often do not meet the narrowly-crafted framework which allows for compulsory licensing, U.S. innovators can have very little confidence in the major investments they make to bring their products to many emerging markets.

It is true that compulsory licensing is a tenet of WTO trading principles and was clarified to address emergency situations as part of the Doha Development round of negotiations in 2000. However, the framework around the issuance of compulsory licenses remains ambiguous and there are few limitations on countries that threaten to break patents under a compulsory license as a negotiating tactic with innovator companies. In addition, there is no clear floor for compensation offered to innovator companies whose patents are issued under a compulsory license. When the government of Thailand issued compulsory licenses around a number of drugs designed to address AIDS and heart disease in 2006 the level of compensation provided

to the innovator companies that held the patents was 0.5% of the sale of the generic versions that were promoted by the government.

What is fairly clear within the context of rules for compulsory licenses is that they are designed to be issued to address "emergency" situations in countries where efforts to legitimately license products have been exhausted. In reality this is rarely the case. Brazil's model of threatening compulsory licenses as a negotiating tactic with pharmaceutical companies is well known and is an area where the U.S. Government has frequently intervened to dissuade the Brazilians from using this tactic. An ironic twist to Brazil's aggressive posture in promoting the use of compulsory licenses was highlighted in their own statements to the WIPO Standing Committee on Patents in 2010 when they complained that it took almost two years for their pharmaceutical industry to develop and produce a drug under compulsory license because the information necessary was not "sufficiently revealed to allow its production as promptly as desired." Basically, by issuing a compulsory license they made it impossible to develop a sensible commercial relationship with the innovator company that probably would have brought a higher quality product to the market sooner in Brazil.

In a recent case that has garnered significant attention, India has for the first time issued a compulsory license related to a treatment for liver and kidney cancer produced by Bayer. While Bayer is a German-based firm, its U.S. subsidiary held the patent for the product in India. This case is noteworthy for a number of reasons and places a challenge before the U.S. government to contain the spread of similar actions based on India's decision.

Exemptions from Infringement: Similar to provisions that specifically exclude categories of technology from patentability, several countries have established rules that explicitly shield patent infringers from any legal recourse. Brazil is again noteworthy in this regard as it has put in place several excessive exemptions to patent infringement. For example, a very wide and vague provision allows for private, non-commercial use of patented technologies that does not "result in prejudice to owner's economic interests." Experimental use related to research is also exempted, as is using patents as a source of new products. Pharmacies in Brazil can also use patented medicines for "individual cases" with no real definition of what that means.

It is of course, important to note, that limited exceptions can be made by countries provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner. However, a wide swath of exemptions such as those present in Brazil can conspire to create significant uncertainty with patent owners and undermine the important premise of allowing patent owners to reasonably exploit the rights that come with the granting of a patent.

Patent subsidies: The Chinese government subsidizes the development of domestic technologies by providing direct financial support for Chinese companies to file foreign patent applications. China is seeking to expand this program dramatically and hopes to generate 2 million patent filings a year by 2015.

"Compliant Non-compliance"

Beyond specific practices that often amount to direct violations of WTO rules or individual Free Trade Agreements, we also see instances where the laws countries may have on the books appear to be satisfactory and/or not specifically prohibited, but the situation on the ground for U.S. companies is still extremely unbalanced based on what amounts to small legal hooks that weaken patent enforcement. These practices take a variety of forms and are often part of larger national initiatives.

Indigenous Innovation: Under the framework of promoting Indigenous Innovation, China is discriminating against foreign competitors by limiting the ability of non-Chinese IP owners to access the Chinese market. *Indigenous Innovation Product Accreditation* systems proposed in China would impose onerous and discriminatory requirements on companies seeking to sell to the Chinese government and state-owned enterprises. These policies pose a significant threat to U.S. industries ranging from software to manufacturing. The U.S. Government and industry have taken a hard-line on these proposals and the Chinese agreed to limit them at the 2010 JCCT meeting, but the situation on the ground appears to have not changed sufficiently.

Patent Office Weakness or Inconsistency: Even if countries appear to have patent laws that may be adequate, it is often the case that the patent offices in those countries are extremely over-burdened and under-staffed. It commonly takes 8-10 years to get a patent approved in Brazil and with 4 co-equal, but not well-coordinated regional patent

offices in India, it is not unheard of to get opposite outcomes for similar applications filed in different offices.

This exacerbates the overall ability of patent owners to ultimately protect their innovations when patent quality is poor and multiple challenges can be mounted to the validity of a patent, often due to weak processes in the national patent office. This is an area where the experience and expertise of the U.S. can be a huge asset. The USPTO has been training and collaborating with patent offices in developing countries for years, and with the AIA as the global model for patent quality and efficiency, we should look to redouble these efforts.

Pre-grant opposition: Countries such as India, Australia, New Zealand, Vietnam and others have a system that allows third parties to formally oppose patent applications as soon as they are published by the patent office. This practice has led to obvious abuse as competitors and others seeking to create barriers for U.S. companies can delay and confuse the patent application process by overwhelming examiners with information which is not relevant to the process that should exist between the applicant and the patent office. Opening the patent application process to third parties exposes it to harmful and unnecessary delays.

Weak Judicial Enforcement: Just as patent offices in many emerging markets are struggling to modernize and meet the demands of an explosion of complex applications, the courts in those countries are struggling to handle complex cases of patent enforcement. Courts in India have just begun to handle patent cases and the standards for interpreting patent claims, enforcing injunctions and other matters are still in their infancy. The default for many U.S. companies seeking to enforce their patents in court is an exceedingly long process that rarely results in any type of protection.

Making matters worse, in China, the Supreme Peoples' Court has urged lower courts not to issue preliminary injunctions for "complicated technologies" such as biotechnology. And in China, is it common for senior party officials to personally attend major patent cases adding pressure on judges when the interests of the state are at stake against foreign companies.

This is an area where the U.S. has focused over the years and efforts such as those led by Chief Judge Randall Rader of the U.S. Court of Appeals for the Federal Circuit have made a tremendous difference. Judge Rader has traveled frequently to China and other countries promoting judicial independence and specialization for complex patent cases.

Patent Term Adjustment: The WTO TRIPS Agreement requires a patent term that must be at least 20 years from the date of patent application. Because the regulatory approval process is often very long, most developed economies have instituted procedures whereby patent owners can seek an extended period of patent protection to partially compensate for exceedingly long approval processes that can significantly erode the effective life of the patent. This type of balance allows patent owners to have the time and market exclusivity which is typically necessary to justify the huge underlying investment made to develop and bring a product to the market. The reality is that most major emerging markets do not offer any form of patent term extension, these include China, Brazil, India, Chile (despite it being a requirement of the U.S.-Chile FTA), Canada, Argentina, New Zealand, South Africa and others.

Conclusion

Mr. Chairman, the challenges and opportunities for U.S. companies in global markets are both extraordinary. This committee has raised an important issue that impacts countless U.S. businesses of all sizes and is at the core of our overall global competitiveness. It is very clear that U.S. companies face tremendous complexity and difficulty as they seek out global markets. But as the most competitive and innovative nation in the world, there are an even greater number of opportunities.

Congress is presented with a tremendous opportunity to promote a strong global environment for patent protection based on its work to modernize and strengthen our system in the U.S. U.S. companies do not just seek to protect their innovations at the USPTO and then stop, they move on to countless other global markets to bring their innovations and breakthroughs to the millions of consumers outside our borders. We should look to support these efforts by promoting the strong patent laws and practices we have developed in the U.S. through the America Invents Act and its continued implementation in markets around the world.

I truly appreciate the opportunity to participate in this hearing and look forward to any chance to support the work of the Committee in the future.

Mr. GOODLATTE. Thank you, Mr. Israel. Mr. Murphy, welcome.

TESTIMONY OF SEAN P. MURPHY, VICE PRESIDENT AND COUNSEL, INTERNATIONAL GOVERNMENT AFFAIRS, QUALCOMM INCORPORATED

Mr. MURPHY. Good morning, Chairman Goodlatte, Ranking Member Watt, and other Members of the Subcommittee. It is an honor to testify this morning. I am grateful for the opportunity.

My name is Sean Murphy and I manage international policy issues at Qualcomm, including intellectual property and international trade. Let me begin by thanking Members of the Subcommittee for your important efforts to support American innovation through strong intellectual property laws. Thank you also for your recognition of the challenges that U.S. patent holders confront in other countries which threaten America's competitive edge, technology leadership, and jobs.

The patent system has been critical to Qualcomm's success. Founded in 1985, Qualcomm started with seven engineers in a living room with ideas to improve mobile communications. At the time, mobile technologies were expensive, unreliable, and limited only to voice calls. Our founders were determined to do better and pioneered a new digital communications technology called code division multiple access, or CDMA. Today we are a successful global company of more than 23,000 employees, 65 percent of whom are engineers, with 73 locations in the U.S. and 172 locations worldwide. More than 90 percent of our global revenues are earned outside the United States but nearly 70 percent of our employees work here.

The adoption of CDMA has exceeded our expectations and helped to drive a global revolution in mobile technologies and services. Today there are 6 billion mobile connections in a world of 7 billion people.

Qualcomm's business model concentrates on two key areas. First, we design state-of-the-art semiconductors and software which are the brains of today's advanced mobile phones, tablets, e-readers, and other mobile devices.

Second, we broadly license our portfolio of U.S. and foreign patents to virtually every manufacturer in the mobile industry. We reinvest approximately 20 percent of annual global revenues in R&D, which equated to about $3 billion last year and over $19 billion since our founding.

These investments produce new inventions that drive what we call a virtuous cycle of innovation. Our business model enables a $1.3 trillion global ecosystem, promotes competition and choice, and benefits consumers. Qualcomm is one of countless innovative technology companies that rely on strong patent protections to drive U.S. jobs, economic growth, and exports.

According to the Department of Commerce report that Congressman Watt mentioned, IP-intensive industries account for over one-third of U.S. GDP and 40 million American jobs. IP licensing generated a trade surplus of $84 billion last year. To sustain this impressive growth, American innovators need fair market opportunities and adequate patent protections globally. However, foreign governments and industries try to achieve unfair competitive advantage through a variety of protectionist policies. These measures aim to promote indigenous innovation or exclude, minimize, or devalue American technologies.

A few examples: pressure to reduce licensing fees or royalty rates and make other concessions; local working requirements, such as local manufacturing in order to preserve patent rights; exclusion of certain technologies from patent protection; the use of homegrown technical standards to benefit domestic technology or industry; and

the threat of antitrust enforcement to force the transfer of patented technologies on unfair terms.

Beyond these specific practices, which are not adequately addressed by existing treaties or trade agreements, we see a growing trend worldwide to weaken patent protection. It is imperative that the United States lead by example and send consistent messages to our trading partners about strong patent laws and fair market access for American innovators. Governments, including our own, should not favor or discriminate against any particular business model, technology, or means of commercializing intellectual property. In sum, policymakers should refrain from picking winners and losers, and laws and policies should be "business model-neutral" in their design and their effect. Yet the opposite is the norm in many countries critical to U.S. companies.

We should vigorously expand and enforce international agreements and trade policy dialogues in order to promote a level playing field for American innovators and job creation. This approach will serve us well today, while also encouraging the next generation of U.S. inventors and U.S. employment.

Thank you again for the opportunity to appear today to share Qualcomm's perspectives. I welcome your questions. Thank you.

[The prepared statement of Mr. Murphy follows:]

Statement by

Sean P. Murphy
Vice President and Counsel, International Government Affairs
Qualcomm Incorporated

Prepared for the hearing on

"International Patent Issues: Promoting a Level Playing Field
For American Industry Abroad"

Before the

Subcommittee on Intellectual Property, Competition, and the Internet
Of the Committee on the Judiciary
U.S. House of Representatives

April 26, 2012
10.00 a.m., 2141 Rayburn

INTRODUCTION

Chairman Goodlatte, Vice Chairman Quayle, Ranking Member Watt, and Members of the Committee, thank you for holding this important hearing. My name is Sean Murphy, and I am Vice President and Counsel of International Government Affairs at Qualcomm, based at the company's headquarters in San Diego, California. For the past decade, I have managed a broad range of international public policy issues for Qualcomm, including intellectual property, international trade, and innovation.

I am honored to appear today before this distinguished body to discuss the importance of strong patents rights, both internationally and domestically, to Qualcomm and other American companies that compete in the global marketplace. U.S. technology leaders such as Qualcomm are key contributors to economic and job growth in this country. According to a report published in March 2012 by the U.S. Department of Commerce, America's most IP-intensive industries in 2010 generated direct employment of 27.1 million jobs and an additional 12.9 million jobs through indirect activities associated with these industries. In total, these 40 million jobs represent 27.7 percent of America's workforce. In 2010 these IP-intensive industries accounted for $5.06 trillion in value added, or 34.8 percent of U.S. gross domestic product.

The United States currently leads the world in technological development, and maintaining that leadership position depends critically on the domestic and foreign laws, policies, and procedures that define the global competitive landscape. We must ensure that when U.S. companies like Qualcomm invent pioneering technologies, they can obtain robust patent rights throughout the world to protect those technologies. We must also secure and preserve the right of U.S. patent owners to license and enforce their rights on a global basis without unfair restrictions that could impede exports or artificially inhibit competition and consumer choice. If policymakers (at home or abroad) restrict market access to the benefit of local champions or weaken patent rights to promote a specific business model, we risk losing the innovative and competitive edge that has served this country so well throughout its history.

QUALCOMM OVERVIEW

Some of you may not be familiar with Qualcomm. Although our technologies and intellectual property have helped power the wireless communications industry for nearly two decades, we do not manufacture consumer devices. We once did: when Qualcomm was a young company and our early technology was unproven, we developed and sold equipment and devices to promote the deployment of our wireless technology. However, as our technology gained commercial acceptance, we sold two of our manufacturing divisions and refocused our business on two key areas, (i) fundamental technology research and development to ensure that our wireless technology is perennially state-of-the-art, and (ii) the design and sale of high quality semiconductor chips and software for wireless communications devices. Today, we are the sixth largest semiconductor supplier by revenue and the world's largest "fabless" semiconductor company – meaning that we invest heavily in research and development, and design our chips in-house, but do not own or operate our own semiconductor fabrication facilities. Instead, Qualcomm contracts with outside foundries to produce our chips based on our designs, which embody our intellectual property.

At Qualcomm, we attribute much of our early success and growth to America's gold standard patent system. Qualcomm's founders are the quintessential example of the storied American "inventors in the garage" who built a multi-billion dollar company on the foundation of highly innovative technology and strong patent rights. Since our founding in 1985, Qualcomm has evolved into a global business that derives more than 90 percent of its revenues outside the United States. Last year, our worldwide revenues were nearly $15 billion, with roughly 60% resulting from the sale of chipsets and 30% from licensing revenues. We license our portfolio of wireless technology patents to more than 210 companies throughout the world – including in China, Taiwan, India, and Europe – and invest more than 20 percent of our revenues annually in research and development.

Even though Qualcomm is a global company, 70 percent of our 23,000 employees (65 percent of whom are engineers) are based in the United States. In that regard, Qualcomm exemplifies the critical importance of an IP-based economy. Through ongoing investments in research and development (R&D) and broad-based licensing of our patented technologies, Qualcomm is able to drive billions of

dollars in exports, while creating thousands of well-paying jobs for U.S. workers.

QUALCOMM TODAY: A GLOBAL LEADER IN WIRELESS TECHNOLOGIES

Despite its humble beginnings, Qualcomm is today a world leader in developing state-of-the-art wireless technologies, including the Code Division Multiple Access ("CDMA") and Orthogonal Frequency Division Multiple Access ("OFDMA") cellular technologies that are used worldwide for wireless voice and mobile broadband communications. Qualcomm's CDMA and OFDMA technologies are integral to hundreds of mobile phones, tablets, e-readers, mobile applications, and a host of other wireless devices and services.

Qualcomm technology powers the third and fourth generations of cellular networks (commonly known as "3G" and "4G") operated by wireless carriers throughout the United States and around the world. These carriers' networks enable hundreds of millions of people, in rural, suburban, and urban areas alike, to enjoy ubiquitous and highly advanced mobile voice and broadband data services virtually everywhere they go.

Qualcomm has an extensive portfolio of U.S. and foreign patents relating to 3G and 4G digital wireless communications technologies, and the company continues to apply for and obtain patents in the U.S., Europe, China, Japan, South Korea, Brazil, India, Taiwan and other countries around the globe. Qualcomm broadly licenses its technology to more than 210 manufacturers worldwide who make network equipment, handsets, and other consumer devices and develop applications for cellular networks based on 3G and 4G technologies.

Since its inception, Qualcomm has invested more than $19 billion in R&D. In fiscal 2010 alone, Qualcomm spent twenty three cents out of every dollar in revenue – or a total of $2.55 billion – on R&D. By dedicating resources of this magnitude to new R&D, Qualcomm has developed many of the new wireless technologies that are now driving unprecedented growth in mobile voice and broadband services.

Qualcomm's chipsets support all the major frequency bands, the full gamut of standardized, globally harmonized 3G and 4G wide area mobile broadband and cellular technologies, Assisted GPS (A-GPS) location tools, Bluetooth, Wi-Fi, and many mobile device operating systems, such as Android, Windows Phone 7, and Qualcomm's own Brew Mobile Platform. We produce chips that the world's leading phone manufacturers use in their 3G devices. We're also producing chips based on the latest 4G Long Term Evolution (LTE) technology, but that remain compatible with existing 3G technologies to ensure wide coverage for multi-mode LTE/3G devices.

Qualcomm currently employs workers in 172 locations in over thirty countries. As noted above, however, 70 percent of our 23,000 employees are located in the United States. Our headquarters and the majority of our employees are in San Diego, but over the years we have opened additional facilities across the United States, including in Massachusetts, New Jersey, North Carolina, Texas, Colorado, Georgia, and Silicon Valley. We are proud to have been named one of FORTUNE's "100 Best Companies to Work For" for 14 consecutive years.

As one of the largest employers in San Diego, Qualcomm plays a significant role in shaping and contributing to the dynamics of the San Diego regional economy. According to a study conducted in 2008 by the San Diego Regional Chamber of Commerce, Qualcomm's total economic impact to the San Diego region was approximately $5.5 billion in 2007. Also from the same study, Qualcomm employed over 10,000 people directly in San Diego in 2007, and money spent by Qualcomm and its employees created and supported over 26,000 jobs touching a variety of goods and services in San Diego County. As of 2007, Qualcomm was responsible for economic output equal to approximately 3 percent of the Gross Regional Product of San Diego County and supported an estimated 2.4 percent of total jobs. And of course, Qualcomm's contribution to San Diego's economy is much more significant today, given our continuous, rapid growth.

Today, greater San Diego is home to hundreds of telecommunications companies, from startups to leading research and development facilities of global telecom companies. This is in sharp contrast to what existed in 1985. Today, the telecom industry boosts the region's economy with thousands of high-paying jobs. Qualcomm has contributed to the creation of this industry cluster through both spin-offs

and partnerships with our licensees.

Because of the technologies we've created at Qualcomm, people the world over are interacting with each other in ways and numbers that may have seemed unimaginable in 1985. In 1999, in the 2G era, there were approximately 350 million mobile subscribers worldwide. Thirteen years later, in the era fueled by Qualcomm's 3G technology, there are now more than 6 billion wireless connections globally in a world with 7 billion people.

And this cellular technology is not limited to those who can afford smart phones. Approximately 2 billion people in the developing world are living on less than $1.25 a day, yet many of them have a mobile device. Indeed, from here on, access to the internet for the vast majority of the world's population is going to be through the cell phone. As economist Jeffrey Sachs notes, poverty is equated with isolation in many parts of the world and results from "lack of access to markets, to emergency health care services, access to education, the ability to take advantage of government services and so on. What the mobile phone – and more generally IT technology – is ending is that kind of isolation in all its different varieties." Mobile technology empowers individuals at all economic levels and in all corners of the world, and changes the trajectory of people's lives.

With more than $1.3 trillion in annual industry revenue, mobile phones have become the largest technology and information platform in history. And one year ago, we reached a key tipping point: the number of mobile broadband Internet subscriptions surpassed fixed line users. Mobile data usage, which is directly enabled by Qualcomm's technologies, is growing rapidly. Last October, the Federal Communications Commission projected that mobile data usage would grow by more than 35 times from 2009 to 2014. Since Qualcomm's founding just over 25 years ago, the mobile phone has evolved from a means of voice communication into an extraordinarily powerful mobile computer. Qualcomm's innovative CDMA technology helped drive that transformation.

QUALCOMM'S EARLY DAYS: PROOF THAT AMERICA'S PATENT SYSTEM WORKS

From its inception, Qualcomm has been driven by a desire to make dramatic changes in the way people work, live and learn. Qualcomm was formed in July 1985 at a meeting of our seven founders in Dr. Irwin Jacob's San Diego home. At the time, available wireless technologies could not support reliable and affordable service. Our founders started without a specific product in mind, but with the determination to solve this problem by creating new and revolutionary communications technologies. Within a few months of founding Qualcomm, Dr. Jacobs realized that the principles upon which CDMA is based (known as a spread spectrum technology) could provide a significant advantage over time division multiple access (TDMA) digital technologies, which were, at the time, being proposed within the wireless industry to replace the existing analog technology. Qualcomm's founders were convinced that by enabling reliable, high quality, and affordable service, CDMA had the potential to cause a dramatic leap forward by the then nascent wireless industry.

In Qualcomm's early days, CDMA was widely perceived as a promising but risky technology. Commercializing our vision for CDMA was a difficult and costly process, and by necessity, we sought funding from numerous sources. Our core patents were our most valuable assets in these early days, helping to secure funding, offering a source of future revenue, and safeguarding our technologies against theft. Moreover, our early patent and technology licenses provided necessary funding to continue our development of CDMA technology.

Qualcomm first deployed its technology in the transportation industry. Between 1985 and 1988, Qualcomm developed a wireless, two-way messaging and positioning system that would enable trucking firms to closely track their drivers' progress while enabling drivers and dispatchers to send messages to each other. This system, named OmniTRACs, has grown to become the largest satellite-based commercial mobile communications and asset-tracking system for the transportation industry.

Based on the revenues generated by OmniTRACs, we were able to turn our attention once again to commercializing CDMA. Companies around the world had studied CDMA technology but had encountered technical difficulties. By 1989, Qualcomm was able to demonstrate that we had solved the

critical technical problems. Because CDMA offered a significant increase in spectrum efficiency – i.e., that is, the number of subscribers a carrier could support in a given allocation of spectrum – carriers offered support and urged their manufacturers to work with us.

Qualcomm quickly realized that licensing its patented CDMA-related technologies to existing suppliers of wireless consumer devices and system network equipment would accomplish two important objectives. First, it would provide Qualcomm funding from upfront license fees that would enable Qualcomm to continue and grow its CDMA research and development (R&D) program and fund our costs in developing integrated circuits for commercial handsets and system network equipment. Second, and perhaps even more importantly, it would develop an ecosystem of licensed manufacturers committed to Qualcomm's CDMA technology. Qualcomm even organized teams of its licensees to help conduct and monitor test systems that Qualcomm installed in San Diego.

The first commercial CDMA network began operation in the fall of 1995 in Hong Kong. Still, there remained considerable doubts about CDMA and strong opposition from members of the wireless industry who were invested in other technologies. Well-known manufacturers of handsets and infrastructure equipment, such as Nokia, Ericsson and Motorola, had invested in other established technologies, and were reluctant to switch to CDMA network equipment and handsets. As a result, as I mentioned earlier, Qualcomm had to build and operate its own infrastructure and handset businesses until CDMA technologies were well established.

In the early 1990's, Qualcomm began to work closely with the Electronics and Telecommunications Research Institute (ETRI), an agency of the South Korean government, to finalize commercial specification for a CDMA network to be deployed in South Korea. Based upon that work, and Qualcomm's licensing of its technology to key Korean manufacturers such as Samsung, LG, and Hyundai, CDMA was adopted by the South Korean government as the next generation of wireless networks in that country. CDMA was deployed in South Korea in 1996. Soon, South Korea became renowned for having the most advanced wireless networks in the world, a reputation that persists today. Based on CDMA's success in Asia, CDMA was ultimately adopted in the United States and in many other venues around the world.

Despite breaking into Korea and the United States, Qualcomm continued to face intransigence in the European regulatory and standards bodies. Established European interests were intent on locking American technology out of the European marketplace. But, through dogged advocacy and the inevitable effect of free market forces when presented with a superior technology, CDMA was eventually allowed in Europe as the third generation standard and allowed to compete with the TDMA-based 2G wireless technology then prevalent in Europe.

As mentioned earlier, as our technology gained commercial acceptance, we made a strategic decision to sell the handset and infrastructure divisions of Qualcomm and concentrate on new, advanced core wireless technologies and designing and selling integrated circuits and software to consumer device and system network equipment manufacturers. By specializing in innovation, we were able to better utilize our resources to advance the technology. Moreover, because we elected early on to license broadly our patented technologies, we helped drive a far larger, more diverse, and competitive wireless industry, which in turn has fueled limitless opportunities for new forms of economic and social development.

INNOVATION & PATENTS

Qualcomm's fight to gain acceptance and deployment of CDMA was not easy. The established industry players did not want to take on a new technology, particularly one that would enable new competitive manufacturers. Even after Qualcomm built and successfully demonstrated a small CDMA system incorporating its solutions, a Stanford University professor stated that we would not succeed because our technology "defied the laws of physics."

Needless to say, the deep and widely-held skepticism about CDMA made investment in Qualcomm a very risky undertaking. Yet despite enormous odds and unrelenting opposition from entrenched industry participants who were committed to other technologies, Qualcomm ultimately was able to raise the necessary capital to continue its work. Why? Because the patent system offered the promise of market-based rewards if Qualcomm's solutions succeeded and allowed the potential of CDMA to be realized.

If the United States or other governments make the wrong policy choices regarding intellectual property, innovation will quickly be stifled. At Qualcomm, we view technological innovation as a chain with value added at each stage. It starts with an invention – often, a disruptive invention that is the necessary first link. However, as Qualcomm's history attests, the initial invention stage, though fundamental, requires numerous additional stages before commercial applications of the invention are even feasible, let alone profitable.

Strengthening – or at least preserving – incentives to innovate, both nationally and internationally, should be viewed today as a top priority for U.S. policymakers. After all, IP has become our number one export. As USPTO Director David Kappos has so aptly put it, intellectual property is "the global currency of innovation." If incentives to invest in basic R&D are weakened and disruptive inventions are never realized, new product development will inevitably decline. American workers and consumers will be worse off, and the United States will risk losing its technological and competitive edge.

Qualcomm's experiences as a small startup company illustrate the close relationship between IP protection, innovation, and economic growth. In our early days, Qualcomm's success was dependent on its ability to negotiate license agreements with some of the largest companies in the world at that time – AT&T, Ericsson, Sony, Panasonic, and Motorola. These agreements provided upfront license fees for funding Qualcomm's early R&D and the potential of royalty income to reward Qualcomm's shareholders could our technology be successfully deployed.

How could such a young company, even with a great new technology, navigate a marketplace dominated by these industry giants? More importantly, how could we convince these far more powerful players to license our technology? The answer was, and still is, rooted in our strong system of patent rights and remedies.

Of course, Qualcomm's story does not end with the acceptance and eventual success of CDMA. Ours is a dynamic competitive industry where no company can afford to take a breath and rest on its success. Year after year, Qualcomm makes enormous investments, averaging more than 20% of its annual global revenues in R&D – a much greater level of investment than most technology companies. We see our

business model as a continuous "virtuous cycle" of innovation. We invent, and we protect our inventions through U.S. and foreign patent rights; we license our patent portfolio to others; we collect royalties from our licensees and reinvest those royalties in more R&D that produces new inventions.

Today, Qualcomm's success and continued ability to innovate is tied to the growth of the entire wireless ecosystem. Our licensing program reflects that linkage. We broadly license our patents to propagate our technology. And when we patent new inventions in 3G technology, our existing licensees get the benefit of those inventions without an increase in the royalty rate they pay to Qualcomm. Looking beyond 3G, we have actively pushed the envelope and contributed to the launch of the fourth generation (4G) of wireless innovations – a technology called Long Term Evolution or LTE. Our R&D efforts have translated into one of the most significant portfolios of LTE patents among all industry participants.

Critical to innovation is the patent-based system of risk and reward. Qualcomm's shareholders allowed us to take risks based on the confidence that, if we did successfully innovate, a strong patent system would allow us to earn a reasonable return on investment. But access to funding is scarce, and it is getting scarcer. We need to ensure that risk capital is available for research, development and commercialization. If we create significant uncertainty as to a patent's value or enforceability – whether through weaker IP rights, regulatory intervention, or other policy changes – capital will cease to flow to innovators, and technological development will decline – affecting our prosperity and ultimately the world's quality of life.

All stakeholders – industry, governments, NGOs, academia and other international institutions – should have a shared interest in preserving incentives to create and propagate new and useful inventions. As Qualcomm's co-founder and original CEO and Chairman Dr. Irwin Jacobs once said: "Without such incentives, we will measure the cost by the bells that don't ring, the cures that are not developed and the technologies that are not invented. In the long run, society will be the poorer for it."

Today, the United States invests more in intangible assets than any of our major trading partners. Our intangible assets now exceed tangible assets by more than 20 percent – a trend that is likely to continue

and even accelerate. As a result, we are the envy of the world. Developed and developing countries are actively trying to emulate our success. China is a notable example. According to China's patent office, in the late 1990's, foreign patent applications exceeded domestic applications by a significant margin. Foreign companies like Qualcomm were applying for patents in China at a much greater pace than Chinese companies. However, by 2001, Chinese applicants caught up to their foreign counterparts, and in recent years, Chinese companies have filed twice as many patent applications in China as foreign companies.

Chinese entities have also increased dramatically patent filings outside of their home borders. This move to escalate patenting activity is part of China's broader plan to build rapidly an innovation-based economy, comparable to our own. With the support and subsidization of the Chinese government, leading Chinese technology companies, such as Huawei and ZTE, have emerged as important players in IP-intensive industries.

CHALLENGES TO U.S. INNOVATORS AND PATENT RIGHTS

Because Qualcomm's business is global, we need to maintain constructive relationships with governments around the world. As a result, I will refrain from identifying any government or country by name and focus on the types of laws, policies, and governmental action that can complicate our ability to do business, conclude patent licensing and other business agreements with customers, or collect royalties from business arrangements outside the United States.

Broader Trends Toward Weakened Patent Rights and Restricted Market Access

Today, U.S. innovative leadership and competitiveness are threatened by at least two forces. First, our trading partners are understandably eager to emulate IP-intensive U.S. industries on the path to technological leadership. That's fine, and even welcome, as long as success is achieved through innovation and competition on the merits. Unfortunately, however, we see efforts by foreign governments and competitors to achieve technological and commercial dominance through domestic preferences, market access barriers, and other protectionist measures.

Second, there is a growing trend, perhaps unintentional but certainly misguided, to devalue intellectual property rights in the United States and worldwide. Finding the right balance between IP rights and competition can sometimes be difficult. Today we see troubling signs that the proverbial pendulum is swinging toward a weaker patent system, certainly in emerging economies, but also in advance, industrialized economies like the European Union and even the United States. As a company that owes much of its success to strong U.S. patent rights – as contemplated in our Constitution and shaped by more than 200 years of laws and jurisprudence – we find this trend profoundly troubling. And we fear the potential consequences for the U.S. economy and competitiveness as a whole, for job creation, and for our dynamic culture of innovation.

Calls for weaker patent rights and remedies are driven by different perspectives and objectives. There will always be IP skeptics who are ideologically opposed to strong property rights and simply do not believe in the nexus between intellectual property, innovation, and competition. Increasingly, however, efforts to weaken and devalue patent rights are driven by short-term commercial self-interest. Even in the United States, we see certain companies and industry coalitions advocating legislative and regulatory measures to weaken and devalue patent rights as a means of promoting specific business models.

These IP critics are, in effect, asking policy makers to favor large implementers of new technologies over non-manufacturing patent owners that license their technologies – for example, through measures that would limit remedies for patent infringement or restrict the patent owner's ability to license its rights through bilateral, market-driven negotiations. To pick winners and losers among different participants in America's innovation economy is a dangerous proposition, particularly in a highly competitive global marketplace. What's more, doing so would undermine the democratic system of risk and reward envisioned by our founding fathers.

The so-called "smartphone patent wars" we are currently observing have fueled much of the recent mythology of a "broken" patent litigation system. Although characterized as an unprecedented surge in patent litigation, these cases – which implicate a handful of large mobile device manufacturers and operating system software providers – are merely the latest in a series of "battles of the titans" that have

periodically erupted in times of intense technological change. The sheer number of parallel U.S. and foreign infringement suits filed by these same competitors fuels the perception of patent litigation run amok. Of course, alleged infringers have every incentive to perpetuate this perception by blaming their plight on an "imbalanced" patent system that threatens to stand between consumers and their favorite mobile devices.

In reality, however, the smartphone cases are all part of an interrelated web of lawsuits initiated by a small subset of large incumbent competitors vying to expand their technological footprint and market share. Similar waves of patent litigation have occurred in previous periods of significant technological development, including in the 19th century with the so-called telephone and sewing machine wars. The number of patent lawsuits related to the smartphone business is nearly 100. In the late nineteenth century, the American Bell Telephone Company, founded by Alexander Graham Bell, litigated 587 patent cases, five of which went to the U.S. Supreme Court.

Similarly, the first commercially successful sewing machine also sparked a flurry of lawsuits in the nineteenth century, implicating numerous inventors of complementary technologies, most notably Elias Howe and Isaac Singer. The ensuing sewing machine war was ultimately resolved when the four principal patentees agreed to pool their patents and enter into cross-licenses, which allowed each to compete in the marketplace without the threat of litigation. We are quite likely to see a similar, commercially-driven resolution to the smartphone wars without any need for government intervention or inconvenience to mobile phone users. In fact, the enormous volume of recent patent acquisitions within the smartphone sector may suggest that a cease fire is imminent.

Nevertheless, the recent smartphone disputes have attracted the attention of certain members of Congress, the Federal Trade Commission, the Department of Justice, and foreign antitrust agencies including the European Union's Directorate General for Competition. To a significant degree, this regulatory attention has been prompted by the efforts of certain litigants to encourage government intervention. To the extent competition authorities take the bait and attempt to weaken patent rights, impose price controls, regulate royalty rates or other licensing requirements and restriction, these short-term measures could, in the long run, profoundly limit innovation and make America less competitive.

Throughout its existence, Qualcomm has experienced first-hand similar situations where governments have favored established manufacturers and their technologies over newer, more innovative, but ultimately disruptive inventions. As noted above, our superior technology faced significant resistance in the United States and Europe from entrenched industry participants. Had government regulators chosen to reward industry incumbents over market-driven competition, the smartphone industry might have suffered immeasurably. Certainly, if certain important countries had remained closed to Qualcomm's technology (and its leading telecommunications manufacturers advocated), the wireless ecosystem would not be as expansive and global as it is today.

In fact, the wireless communications sector was largely static in the 2G era between 2000-2005, with a handful of entrenched companies dominating the technology and marketplace. In contrast, 3G technology, driven in no small part by Qualcomm's patent licensing program, has opened the door to a broad variety of new entrants from different parts of the world. The global wireless communications industry has been characterized by explosive growth, constant technological advancement, lower prices, and a pattern of new entrants and shifting competitive leads. During this same period of rapid 3G-driven growth, certain entrenched 2G GSM manufacturers have faltered in the face of new competition. They have failed to keep pace with the level of product innovation displayed by new entrants in the dynamic and fast-changing sector.

Illustrations of Specific Threats to American Businesses Abroad

These broader efforts to restrict market access, weaken patent rights, displace imported technologies and foreign intellectual property in favor of "indigenous innovation" and restrict technology licensors' ability to freely contract with their customers translate into a range of specific public policy measures that threaten to undermine the competitive position of Qualcomm and other U.S. innovators abroad. Some of these governmental measures and actions are summarized briefly below.

1. **Government Interference in Technology Licensing:** U.S. innovators operating overseas from time to time experience overt or informal pressure from foreign governments

demanding concessions to reduce the price of our patented technologies below values established by the global marketplace, whether in the form of reduced licensing fees or royalty rates. Furthermore, foreign governments may not allow a U.S. innovator to license its patented technologies to domestic companies, unless it reduces the price of associated products.

2. **Local Working Requirement:** Even though our international trade agreements prohibit so-called "local working" requirements, certain countries continue to condition patent rights on the existence of domestic manufacturing operations. These requirements are plainly discriminatory and a clear impediment to adequate patent protection and market access for patented inventions.

3. **Restrictions on Patentable Subject Matter:** Substantive differences in patentable subject matter result in Qualcomm's inability to obtain patent protection for certain inventions outside the United States, such as software or functionality that is not embodied in physical medium. These gaps in patent coverage make it more difficult for American companies to protect their innovations abroad and could open the door to copycat technologies that vie for market share. In other instances, governments and private pressure groups have called for price regulation or the non-enforcement, revocation or denial of patent protections for certain types of technologies associated with social benefits, e.g., universal, low- or no-cost access to the Internet for all humanity. Broad exemptions or limitation of this nature will severely impede incentives for innovators to engage in risky R&D and could ultimately result in less technological advancement.

4. **Unique National Standards and Technical Regulations:** To promote domestic industry and technology, some governments have attempted to compel discriminatory changes to international standards or mandate unique local technical standards. Invariably, these efforts claim seemingly legitimate objectives, such as interoperability and data security; however, the ultimate goal is to promote domestic technology and "national champions" and/or devalue or exclude U.S. technology. For example, a foreign company may be excluded from

the technical work of the local standards body, unless it agrees to license its patented technologies on a royalty-free basis or at below-commercially established royalty rates.

5. **Conformity Assessment Requirements:** Certain governments have attempted to appropriate U.S. proprietary technology by imposing "conformity assessment" requirements for products that are imported or incorporate foreign-origin intellectual property. The purported objective of such programs is to ensure that foreign technologies comply with local technical norms, environmental or safety specifications, or product standards. However, in some countries, governments have used these programs to compel U.S. and other foreign businesses to disclose source code or other proprietary information to domestic inspection agencies or government-linked lags, even though the information has little or nothing to do with applicable norms. The governments have refused to accredit qualified labs outside their country to perform these tests or recognize their testing and certification results. In effect, these requirements are a form of forced technology transfer.

6. **Industrial Policy Measures:** Many governments have adopted protectionist industrial policy agendas that more broadly aim to subsidize and promote local innovation, manufacturing, and employment. Examples include measures to:

   i. Suppress demand for patented inventions owned by foreign companies and/or substitute them for locally invented or developed technology in order to give local inventors more opportunity and bargaining power over foreign competitors.

   ii. Compel foreign companies to move their R&D activities to a given country to obtain some preference or benefit or avoid some form of penalties – e.g., by providing that only products embodying domestically invented, developed, or manufactured technology are eligible for government procurement.

   iii. Compel the patent owner to lower royalties or other fees it seeks from domestic licensees. This is tantamount to government price-setting in the form of a royalty regulation that

benefits domestic companies and national champions.

iv. Cause the patent owner to impose lower royalties or other fees on products made or sold domestically, as opposed to products exported or made outside the country.

7. **Questionable Antitrust Enforcement:** When used for protectionist purposes, foreign competition laws are a major threat to American businesses and their proprietary technologies. Although competition and patent laws share a common goal – to spur innovation and promote consumer choice – certain competition authorities are skeptical of patents, which they view as time-bound monopolies. This perspective, when coupled with anti-American, protectionist, or other industrial policy motivations, can create significant risks for American companies that own valuable patents. Indeed, given the severity and often extra-territorial nature of penalties associated with antitrust violations in most countries, and the uncertainty and expense of defending against such allegations, even the threat of a foreign antitrust investigation or enforcement action can prove a powerful stick with which to compel a range of important concessions. Below are examples of questionable antitrust enforcement that aim to benefit domestic technologies and/or industries:

i. Some foreign regulators have accused American technology companies of abusing their market power when they refuse to offer licensing terms that uniquely benefit local industry, regardless of whether such terms are unfair or otherwise detrimental to the U.S. or other foreign company's economic position.

ii. Regulators have initiated formal investigations and enforcement actions against U.S. entities on the basis of a "refusal to deal" or failure to share "essential facilities" on commercial terms that are favorable to domestic competitors.

iii. Foreign competitors and customers of U.S. technologies firms have used, or threatened use of, local antitrust laws to pressure American patent holders to offer concessions (e.g., to forego cross licenses from the licensee of its relevant patents in partial compensation

for the license granted) or waive certain statutory or contractual rights against infringers (e.g., the right to injunctive relief).

There are ample other examples of discriminatory governments policies that support local champions by pressuring the U.S. licensor to transfer its IP on non-commercial terms. While authorities may think this is the right policy for the short-term, many countries recognize that this approach is ultimately harmful to their long-term interests, as their own industries gradually move up the value chain from manufacturers to innovators and owners of valuable intellectually property.

PRESENT FOCUS ON STANDARDS-ESSENTIAL PATENTS

This focus on antitrust regulation has also brought new attention to the work of standards bodies and the concept of standards essential patents. Competition agencies are adopting the negative terminology developed by critics of intellectual property rights. Terms like "holdup" and "lock in" and "royalty stacking" are increasingly used to suggest that they are the direct and inevitable results of a patentee's assertion of its rights. And these agencies are wrongly implying that the mere possession of a patent, particularly one that may be essential to a standard, is sufficient to establish the presence of market power, which in turn is sufficient to justify government intervention. As a result, antitrust agencies in major technology regions, including the United States, European Union, South Korea, and Japan, have initiated antitrust investigations, or threatened to do so. These investigations could result in a significant departure from existing and well-settled antitrust policies, which have recognized the complementary objectives and benefits of intellectual property rights and competition law.

These theoretical concerns have no basis in reality. For over 40 years, the voluntary standards process for wireless technology has evolved to the point of worldwide cooperation among national and regional standards setting organizations in the form of partnerships to develop common standards. These standards, and the competition among participants and new entrants to build conforming products, have led to extremely sophisticated equipment that has been implemented in an efficient, cost-effective manner. In turn, the voluntary industry standard setting process has helped create a very competitive international marketplace.

The growth in sales of these products has been enormous – in fact, much greater than previous generations of products. Moreover, the products offered to the consumer have evolved with new technologies at an astounding pace. Consider the cell phone of ten years ago, compared with today's most advanced smartphones. Continued innovation within the United States and throughout the world depends on viable standards. In this regard, the current consensus-based voluntary system has proven highly effective.

We know of no technical standard whose widespread acceptance has been hindered by holdup or other hypothetical concerns. It is not in the self-interest of patent owners and standards participants. After all, most innovative companies who participate in the standards process are there for the long haul. They want to have input into the technology as it evolves, as well as input into the next wave of technological development. Abuse of the process would be a one-time event: they would be ostracized from the industry, and none of their future contributions would be accepted.

In contradiction to this record of success, misguided calls for government intervention could undermine incentives that drive and reward innovation. Some foreign governments already use guidelines and regulation to skew competitive conditions to benefit home-grown companies. In the United States, antitrust authorities and other policymakers need to consider carefully the broader implications of government intervention that could weaken America's ability to compete in the global economy.

The recent report issued by the U.S. Federal Trade Commission (FTC), just last year, calls upon U.S. courts to alter the balance between patent and antitrust laws in a way that appears to ignore well established legal principles. The FTC's recommendations seem to ignore the will of Congress and the importance of a free market to IP-based economic growth. Among other things, this report recommends some of the very same changes to patent remedies that were ultimately rejected by Congress when it enacted the American Invents Act of 2011. Such regulatory intervention is, in Qualcomm's view, unnecessary and, more importantly, it would undoubtedly upset the balance in the current system, which appropriately allows the marketplace to operate freely.

Further, because such ill-advised recommendations come from a respected U.S. government agency, they could influence foreign government agencies to adopt policies that weaken patent rights or impede the ability of U.S. technology suppliers and patent licensors to negotiate commercial arrangements concerning the intellectual property on reasonable terms, particularly in emerging economies that are currently developing their own intellectual property, antitrust and innovation policies. This could diminish the value and enforceability of multi-jurisdictional patent portfolios owned by U.S. companies and employers of all sizes. We urge U.S. government agencies to consider the broader global impact of their IP-related recommendations before issuing controversial reports, particularly when recommendations to weaken patent rights lack any empirical support.

Qualcomm would also urge competition authorities to consider the commercial self-interests of complainants or advocates for change that could have the effect (directly or indirectly) of weakening patent rights. Companies that use third-party patented technologies to produce their own products and services will invariably seek to obtain those patents at the lowest possible cost. This is true even when those companies own a significant number of patents. Many product and service providers acquire patents to strengthen their competitive position or defend against infringement claims. If their patents are not an important source of profitability and ongoing R&D, they may view third party patent rights primarily as an unwanted cost of doing business.

Governments should recognize that, in a highly diversified global economy, innovation comes in many different forms and business models. Government actions and policies should avoid picking winners and losers and, instead, promote the full spectrum of business models and IP licensing activities that drive technological development on a global scale and will produce jobs in the future. Moreover, policies should aim to incentivize and support the next generation of American inventors, who today toil in their garages, workshops, universities, or corporate laboratories in reliance on the established system of risk or reward embodied in U.S. patent laws.

* * *

In closing, we urge Members of the Subcommittee to keep in mind the likely domino effect of U.S. IP-related policies on American businesses abroad. The U.S. economy has long benefited from the strongest intellectual property laws in the world. America's system of patent rights and remedies is universally recognized as the gold standard, and, as such, it has given us the moral authority and credibility to fight for stronger protection of U.S. innovations in foreign countries. Maintaining that authority is critical in today's increasingly competitive global economy. If the United States weakens patent rights at home or diminishes the rights of certain business models, our ability to press foreign countries to respect American intellectual property will be greatly diminished. Indeed, we will embolden other countries to adopt even more damaging policies that could jeopardize the continued preeminence of America's most productive industries.

Thank you again for the opportunity to appear before this Subcommittee share Qualcomm's views on this critical topic. I look forward to answering your questions.

Mr. GOODLATTE. Thank you, Mr. Murphy. Dr. Sheppard, welcome.

TESTIMONY OF A. CHRISTAL SHEPPARD, Ph.D. J.D., ASSISTANT PROFESSOR, UNIVERSITY OF NEBRASKA COLLEGE OF LAW

Ms. SHEPPARD. Good morning, Mr. Chairman, Ranking Member Watt, and distinguished Members of the Subcommittee. I thank you for the opportunity to appear today before you to discuss international patent issues. I am sincerely honored and humbled to testify before this Committee on an issue of utmost importance to our national economy. I have a strong academic interest in this area;

but also as a citizen of the United States, I, along with every other person in this country, have a personal interest in ensuring a level playing field for American industry worldwide.

As alluded to in that wonderful introduction—thank you very much—I come at this issue from a unique perspective. As was discussed, I have had the pleasure of working as a bench scientist in the field of molecular biology. I am a registered patent attorney. So I have prosecuted patents both nationally and internationally. I have worked within the Federal Circuit and at the International Trade Commission. And I have worked in science policy and most recently in intellectual property policy right here with this very Committee.

So having that background, I can personally attest to the amount of hard work, labor, cost, and time that goes into creating new inventions, including new drugs and how important it is that the intellectual property laws provide a framework so that such research can continue to take place. I know the challenges and intricacies and frankly the headaches involved in obtaining patent protection nationally and internationally and then later enforcing those same patents.

I understand the challenges the courts face in interpreting IP laws. They try very hard but sometimes it is challenging. And I also know—and I do not take lightly—how hard it is to enact the reforms that I have and will continue to propose.

Finally, as I currently teach law students patent law international IP and other issues, students bring me insights that I previously did not have. I hope all of those things will be useful in this conversation.

In my written remarks, I discuss in detail the importance of IP with reference to the American innovators Steve Jobs and Steve Wozniak, the Steves who cofounded Apple Computer. I discuss these two to drive home the fact that the economy of the United States in the 21st century is and will remain based on the ingenuity of we, the people. And that ingenuity of "we, the people" must be protected. The Steves and others built their American empires not upon manufacturing but upon the intellectual property laws that help to protect the fruits of their labor from outright theft and surreptitious free riding.

One of the things I hammer into my students—and I am sure they would say "hammer"—is that patent law does not convey a right to use. Patent law does not convey a right to sell. All a patent gives a patent holder is the right to stop others from making or using or selling or importing or offering to sell. But to be more succinct, all a patent actually conveys is a right to sue.

Unfortunately, that right can be undermined in many ways that are discussed in my written testimony and that were discussed by others here today and that we will continue to discuss. These are the actual companies at this table who have been in the trenches in these issues and with the Administration trying to protect these rights.

Congress has taken many steps in the past, including creating the Special 301 list, to level the playing field globally for IP. I discuss in my written remarks several of the steps that the Congress has taken, including implementing TRIPS, the creation of Special

301, passage of Pro IP, creation of the International Trade Commission which addresses infringing imports, and passage of the America Invents Act.

However, today I think what I am going to talk about—with the time left, which is almost none—the additional hurdles that I think can bear fruit, if tackled. In my written remarks, I detail several places where I think congressional efforts would be the most effective and the Administration to tackle. The summary of my written submission is that a lot of these issues are public policy issues that the Constitution put upon Congress. The courts look to Congress for guidance. However, on the issue of patentability that guidance has not been forthcoming.

Within my written testimony, there is a quote from 1972 with the courts looking for guidance from Congress on patentability issues. That guidance has not come. And most recently, the Supreme Court has again revisited that issue, and narrowed patentability. The companies here will talk about the fact that other countries have been narrowing patentability in various ways or doing things that affect U.S. companies' ability to patent or enforce. In order for the United States to have a legitimate voice in the conversations to stop other countries from narrowing patentability and enforcement, the United States has to, in some ways, put their own house in order. Patentability has to be addressed in the U.S.. Additionally, the U.S. itself is not in full compliance on some IP issues.

I am over my time. From that side of the dais, it seems like a lot more time. From this side, it seems like no time at all. So I will stop talking now.

[The prepared statement of Ms. Sheppard follows:]

Statement of

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Before the

Subcommittee on Intellectual Property, Competition and the Internet

Committee on the Judiciary

United States House of Representatives

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"International Patent Issues: Promoting a Level Playing Field for American Industry Abroad"

Introduction

Chairman Goodlatte, Ranking Member Watt and Members of the Subcommittee, thank you for the opportunity to appear before you this morning to discuss international patent issues. I am sincerely honored and humbled to testify before the Subcommittee today on an issue of utmost importance to our national economy. I have a strong academic interest in this area but also as a citizen of the United States, I, along with every other person in this country, have a personal interest in ensuring a level playing field globally for American industry.

My testimony today will focus on three points (1) the importance of intellectual property to the United States economy; (2) steps the Congress and the Administration have taken in the past, including the Special 301 list, to level the playing field globally; and (3) additional challenges posed to American industry.

The Importance of Intellectual Property to the United States Economy

It is particularly apt that today is World Intellectual Property Day. Annually on April 26th, we celebrate innovation and creativity and how the limited protections that intellectual property confers fosters and encourages innovative and creative endeavors.

World IP Day 2012 focuses on visionary innovators – individuals whose ingenuity and artistry have broken molds, opened new horizons and made a lasting impact. We lost one such visionary this past October, Stephen Paul Jobs, to pancreatic cancer. "Steve" Jobs the co-founder, chairman, and chief executive officer of Apple Inc., was widely recognized as a visionary and one of the pioneers of the personal computer revolution.

The Steves - Steve Jobs and Steve Wozniak - who co-founded Apple Computer together in Steve Job's parent's garage,[1] are a prime example of how the economy of the 21st century is founded in intellectual property. The economy of the United States in the 21st century is and will remain based on the ingenuity of we, the people. The currency and the jobs of this century, especially for the United States, are dependent on effective and efficient protection and enforcement of intellectual property of all forms but particularly patents. iPhones are made in China by a Taiwanese company. The Steves and others built their American empire not upon manufacturing but upon the intellectual property laws that helped to protect the fruits of their labor from outright theft. Without the incentive to invent and innovate that recognition of intellectual property provides with the grant of the limited monopoly, would we have an iPhone 4 or the remarkably similar Samsung

[1] Apple was established on April 1, 1976 by Steve Jobs, Steve Wozniak, and Ronald Wayne. Apple was incorporated January 3, 1977 without Wayne, who sold his share of the company back to Jobs and Wozniak for $800.

Galaxy S2? For the Steve Jobs of the future to flourish, ingenuity must be protected from theft and surreptitious free-riding.

According to the Office of the United States Trade Representative (USTR) fighting intellectual property theft in overseas markets is critical to the livelihoods of an estimated 18 million Americans who work in intellectual property intensive industries.[2,3] With that realization, it is clear that the United States has a significant ongoing challenge to maintain or enhance global respect for and enforcement of intellectual property. The ability of United States companies to compete in foreign (and national) markets depends to a large degree on whether other governments provide adequate and effective protection of our intellectual property and fair and equitable access to their markets. Offshore piracy, infringement and counterfeiting remain challenges for United States companies in countries where the local government is complicit with intellectual property theft with either ineffective laws or lax enforcement.

Steps the Congress and the Administration have taken in the past, including the Special 301 list, to level the playing field globally

Of course nothing that I have just noted about intellectual property's importance to the economy and American jobs is a newsflash to Congress. Practically every Congress in the latter half of the 20th Century and every one in the 21st Century has taken some step toward leveling the playing field for American ingenuity abroad. Five such steps are discussed below: (1) the implementation of Trade Related Aspects of Intellectual Property, (2) the creation of Special 301, (3) passage of the Prioritizing Resources and Organization for Intellectual Property Act, (4) creation of a quasi-judicial proceeding at the International Trade Commission and (5) passage of the Smith-Leahy America Invents Act.

TRIPs

Global international intellectual property conversations culminated in the 103rd Congress with the TRIPs Agreement – Trade Related Aspects of Intellectual Property.

TRIPs was negotiated in the 1986-94 Uruguay Round and introduced intellectual property rules into the multilateral trading system for the first time. It

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[2] USTR Press release May 2011 USTR Releases Annual Special 301 Report on Intellectual Property Rights http://www.ustr.gov/about-us/press-office/press-releases/2011/may/ustr-releases-annual-special-301-report-intellectual-p accessed April 21, 2012.

[3] A recent report, prepared by the Economics and Statistics Administration and the United States Patent and Trademark Office, calculated a higher value of intellectual property to employment within the United States. This report estimated that intellectual property intensive industries directly accounted for 27.1 million American jobs or 18.8 percent of all employment in the United States economy in 2010. This study included trademark, patent and copyright intensive industries. Intellectual Property and the U.S. Economy: Industries in Focus. March 2012. http://www.uspto.gov/news/publications/IP_Report_March_2012.pdf Last accessed April 23, 2012.

was head and shoulders above previous intellectual property agreements, such as the Berne and Paris Conventions, in that TRIPs established minimum standards that all members must respect regarding intellectual property. Moreover, TRIPs encapsulated intellectual property issues together with other trade issues to allow countries to penalize violations of intellectual property protection with sanctions in other trade areas.

TRIPs was a giant step toward global recognition and respect for the intellectual and creative endeavors of others, irrespective of the innovators home country (*e.g.* most favored nation and national treatment requirements).

It has been 17 years since the TRIPs agreement, with full implementation for most of the developed WTO member countries occurring on January 1, 1995 and for developing countries in 2005.[4] There have been many strides toward creating a more leveled playing field for intellectual property around the world but there is still a lot of work to be done.

In many countries there is a glaring gap between what their intellectual property laws state and the customary practices within that same country. Moreover, many countries have laws, that while they are technically compliant with TRIPs, they remain seriously deficient in intellectual property rights protection generally. An example, in the area of trademark protection, is the lack of provisions barring bad faith registration of another party's trademark. This is a reoccurring theme that subverts the hard of work of the innovator company, permitting foreign copies to free ride on the good will of the originator. International cybersquatting also called "registry pirates" often results in costly and lengthy civil litigation over obvious bad faith registrations. This behavior directly harms the consumer who is likely to be confused/fooled into purchasing products of inferior quality. This activity also harms the brand, which is diluted by inferior quality products sold by the free rider that pirate the innovator's trademark.

It is important for the United States to identify those countries that deny adequate and effective protections of intellectual property rights or deny fair or equitably market access to United States industries that rely upon intellectual property protection. This is the function of the Special 301 list.

Special 301

In 1988 Congress enacted Special 301, in its current form, as part of the 1988 Trade and Competitiveness Act. Special 301 was created in an environment when

[4] The self-identified developing countries had until 2005 to implement the provisions of the TRIPs agreement within their national laws. The Least Developed Nations, as listed in the agreement, were given an extension until 1 July 2013 to provide protection for trademarks, copyright, patents and other intellectual property. However, under the transition period for patents for pharmaceutical products, which was agreed on in 2002, least-developed countries will not have to protect pharmaceutical patents until 2016.

United States intellectual property owners were facing piracy and theft at levels insurmountable for individual companies to combat. It was unknown at that time if the negotiations for TRIPs would bear fruit but it was clear that at a high level in the Administration country to country level discussions were necessary.

The Act requires the United States Trade Representative to undertake an annual survey of foreign countries' intellectual property laws and polices and issue a "Special 301" report. The Special 301 report has been completed for every year starting in 1988, with the first issuance in 1989, to identify particularly egregious country-level concerns with intellectual property enforcement.[5] The report is intended to encourage and maintain effective intellectual property rights protection and enforcement worldwide.

The Special 301 report divvies up countries judged to have inadequate intellectual property right protection or enforcement into "priority watch list" countries and "watch list" countries. In 2011, 12 countries were on the Priority Watch List[6] and 28 on the Watch list.[7] By annually publically listing the outlier countries, the Special 301 list shines a spotlight and brings pressure to bear through

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[5] 19 USC § 2242 - IDENTIFICATION OF COUNTRIES THAT DENY ADEQUATE PROTECTION, OR MARKET ACCESS, FOR INTELLECTUAL PROPERTY RIGHTS

(a) In general

By no later than the date that is 30 days after the date on which the annual report is submitted to Congressional committees under section 2241 (b) of this title, the United States Trade Representative (hereafter in this section referred to as the "Trade Representative") shall identify—

(1) those foreign countries that—

(A) deny adequate and effective protection of intellectual property rights, or

(B) deny fair and equitable market access to United States persons that rely upon intellectual property protection, and

(2) those foreign countries identified under paragraph (1) that are determined by the Trade Representative to be priority foreign countries.

(b) Special rules for identifications

(1) In identifying priority foreign countries under subsection (a)(2) of this section, the Trade Representative shall only identify those foreign countries—

(A) that have the most onerous or egregious acts, policies, or practices that—

(i) deny adequate and effective intellectual property rights, or

(ii) deny fair and equitable market access to United States persons that rely upon intellectual property protection,

(B) whose acts, policies, or practices described in subparagraph (A) have the greatest adverse impact (actual or potential) on the relevant United States products, and

(C) that are not—

(i) entering into good faith negotiations, or

(ii) making significant progress in bilateral or multilateral negotiations, to provide adequate and effective protection of intellectual property rights.

[6] Algeria, Argentina, Canada, Chile, China (PRC), India, Indonesia, Israel, Pakistan, Russian Federation, Thailand, and Venezuela.

[7] Belarus, Bolivia, Brazil, Brunei, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, Finland, Greece, Guatemala, Jamaica, Kuwait, Lebanon, Malaysia, Mexico, Norway, Peru, Philippines, Romania, Spain, Tajikistan, Turkey, Turkmenistan, Ukraine, Uzbekistan, and Vietnam. Additionally Italy was on the Watch List but on an out of cycle review.

the potential of economic sanctions on those countries whose law and actions are not in comportment with the international agreements that bind both them and us.

In four days, on April 30th, the United States Trade Representative will release the 2012 Special 301 list.

Since 1989, some countries, such as South Korea and the Bahamas, have laudably instituted measures to ameliorate the concerns articulated in their Special 301 listing and these countries have been removed from the list. Unfortunately, many more countries have been on some combination of the priority watch list and the watch list since the inception of Special 301 (*e.g.* Argentina, Chile, Colombia, India, and Indonesia). These "repeat offenders" provide a special challenge with which the United States Administration continues to struggle.

PRO-IP

Congress passed the Prioritizing Resources and Organization for Intellectual Property Act, better known as "PRO-IP" in 2008. The bill was introduced by then House Judiciary Chairman Conyers and Ranking Member Smith and co-sponsored by now Subcommittee Chairman Goodlatte and Ranking Member Watt. Among many other endeavors to protect intellectual property rights, the PRO-IP created the position of the Intellectual Property Enforcement Coordinator as the point person to coordinate the United States' intellectual property protection efforts. This raised attention to the requisite level to meet the economic importance of intellectual property for the United States. Subsequently, President Obama created a cabinet level committee chaired by the Intellectual Property Enforcement Coordinator to further the Administration's IP protections efforts on a national and international level.

International Trade Commission

In the same time period as the TRIPs negotiations and the creation of the Special 301, Congress created a quasi-judicial entity, through the Trade and Competitiveness Act of 1988. This entity is housed within the International Trade Commission and exists specifically to address imports of foreign goods from producers engaged in unfair trade or in violation of United States patent or copyright law. To date, the International Trade Commission has initiated over 800 investigations and is currently maintaining 32 ongoing exclusion orders for items found to be in violation of United States intellectual property laws. The International Trade Commission provides an effective and relatively quick process for preventing goods infringing intellectual property rights from entering the United States.

Smith-Leahy America Invents Act

Most recently, the Smith-Leahy America Invents Act was passed by this Congress and signed into law by President Barack Obama on September 16, 2011. One of the hallmarks of this law is the transition of the United States from a "first to invent" country to a "first inventor to file" system. This reform, in changing how the

United States determines who is entitled to patent rights, provides a necessary procedural harmonization that will enable the United States to further the goal of consistency and uniformity in international patent law. Harmonization reduces costs and permits increased efficiencies for innovators.

Additional Hurdles for International Intellectual Property

The Administration and Congress have undertaken multiple initiatives to confront international intellectual property theft. Several of these initiatives are detailed above; however, further challenges exist. In my opinion, the following are additional hurdles that require attention: (1) Limitations on Updating TRIPs, (2) Compulsory Licensing, (3) Complications of Obtaining and Enforcing Patents Internationally, and (4) Uncertainty in the Law of "Patentability" within in the United States.

Limitations on Updating TRIPs

As discussed *supra* the TRIPs agreement was a great step forward in providing respect for and international uniformity in intellectual property rights. However, TRIPs may no longer be an effective mechanism to address the residual concerns. Just as TRIPs was born out of frustrations on the limitations of the Berne and Paris Trade Agreements and the Berne and Paris Agreements themselves were born out of frustration on the limitations with smaller multilateral agreements. To move forward the United States is following in the footsteps of history to work outside of the confines of TRIPs in order to devise new trade agreements that transcend the limitation of the current ones. Lessons learned from the successes and failures of TRIPs can be negotiated into more effective agreements without the limitations of prior iterations or the calcified positions of intellectual property outliers. Negotiations on the Trans-Pacific Partnership and the Anti-Counterfeiting Trade Agreement are two such endeavors.

Compulsory Licensing

One of the central tenets of intellectual property law is that the intellectual property rights owner has near complete control over the use of their property. Compulsory licensing turns that right on its head. In specific circumstances most countries have laws permitting their governments to allow the use of the patent rights without the permission of the patent rights holder, mostly in cases of national emergency. TRIPs specifically permits countries to allow for compulsory licensing provided that the use complies with Article 31 which stipulates, *inter alia,* that (1) each compulsory license should be considered on its individual merits, (2) reasonable efforts must have been made to secure a license, and (3) the scope and duration of the compulsory license must be limited and with adequate compensation to the patent rights holder.

While few would argue that compulsory licenses are not justifiable in exigent circumstances, Article 31 and compulsory licensing clearly have the potential of negating the minimum protections hard won in TRIPs.[8]

For example, on March 12, 2012, India gave a license to an Indian company to sell a generic version of a patented Bayer drug. Bayer had a valid and enforceable Indian patent for the drug but the Indian government justified the compulsory license by stating that the cost was too high and the drug was imported into India as opposed to manufactured in country. This was the first such compulsory license in India. If the criteria cited by the Indian government in this case is to become the standard, many other patents are subject to a similar fate. Such conduct can effectively eviscerate all effectiveness from the existing international property agreements. Compulsory licenses have also previously issued in Brazil and Thailand.

Complications of Obtaining and Enforcing Patents Internationally

While the Patent Cooperation Treaty and the United States Patent and Trademark Office's (USPTO) Patent Prosecution Highway have streamlined the process for inventors to obtain rights, the burden of needing to traverse a patchwork of applications, requirements, fees, regulations, and laws inherent in having to obtain patents country by country is extraordinarily burdensome and costly. The complexity is only compounded once rights are established because then the rights must be protected under another patchwork of laws, enforcement mechanisms, regulation, local authorities and judicial procedures on a country-by-country basis.

The Smith Leahy America Invents Act was a necessary part of a process which may one day culminate in a process for granting a global patent - one stop shopping - granted in all member countries and enforceable in all member countries. The USPTO is working within the current international framework to assist rights holders to more efficiently obtain rights internationally. The work sharing program holds great promise. Programs such as this should be expanded but first more international patent law harmonization must occur. In my opinion, the United States should work continuously toward that ultimate goal.

Of course, obtaining rights, while fundamentally important is a hollow victory if there is no effective means of enforcement. As I say to my law students, all

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[8] TRIPs contains multiple potentials for countries to limit the rights conferred, such as: Article 30. Exceptions to Rights Conferred.

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Compulsory licensing is just one avenue that could negate the minimum standards of the TRIPs agreement.

a patent gives you is the right to sue. Too often when the violation occurs in a foreign country, that is a right without a remedy. The United States should continue to strive to bring harmonization in enforcement of rights and the utilization of international crime authorities in the pursuit. Entities such as Interpol and Europol have been essential in enforcement. Greater resources in those areas may prove effective for combating intellectual property theft on the international scale.

Uncertainty in the law of 'patentability' within the United States

Over the last 10 years, the United States Supreme Court has become increasingly active in the field of intellectual property law. In the past, the Supreme Court rarely granted certiorari in intellectual property cases.[9] Absent Supreme Court review, the Court of Appeals for the Federal Circuit, the court with specialized and exclusive nationwide jurisdiction over patent and trademark matters, was, by default, the last word on patent matters. Thus, the Federal Circuit effectively determined the interpretation of most of the nation's intellectual property laws.

The recent attention of the Supreme Court to intellectual property, particularly to patent matters, has upset some previously settled notions of the scope of intellectual property.

In March 2012, the Supreme Court put a question mark in academia and industry's understanding of what is worthy of a patent right – so called "patentable subject matter".[10] *Mayo v. Prometheus*, is the Supreme Court's second decision concerning patentable subject matter in two years. In this case, the Supreme Court interpreted Congressional intent to be narrower than the practice of the United States Patent and Trademark Office and the Court of Appeals for the Federal Circuit over the last decade. Perhaps the Supreme Court's interpretation of Congress's intent is correct; however, since 1972, the Court has been begging for more clarity from Congress on the matter of patentable subject matter.

> *If these [computer] programs are to be patentable, considerable problems are raised which only committees of Congress can manage, for broad powers of investigation are needed, including hearings which canvass the wide variety of views which those operating in this field entertain. The technological problems tendered in the many briefs before us indicate to us that considered action by the Congress is needed.*[11]

When that clarity was not forthcoming, the courts, including the Court of Appeals for the Federal Circuit "found" it in places and in ways that arguably Congress did not intend. This is clearly a case of the Court's directing policy through

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[9] From 1970-1979, the Supreme Court decided 4 patent cases; from 1980-1989, 7 patent cases; from 1990-2000, 10 patent cases; from 2000-2009, 12 patent cases; from 2010-2012, 6 cases thus far.

[10] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (U.S. 2012)

[11] Gottschalk v. Benson, 409 U.S. 63 (1972), pg. 409

broad interpretations of legislative intent that were not stated directly in the statute.

Such narrowing of intellectual property ***within*** the United States has implications internationally. The narrowing of patentable subject matter within the United States could be utilized by other countries to justify their narrowing of the scope of inventions entitled to patents - for example laws in India and the Philippines denying patentability on new formulations of existing medicines. [12]

The Supreme Court is not at fault. Particularly in the area of patentable subject matter, the Court has been attempting to fill a void while waiting for Congress to speak directly on these issues. The Constitution states in Article 1 Section 8 Clause 8 that "The Congress shall have power...[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." For decades, the Courts, not Congress, have been deciding what realm of activities "promote the progress of science and useful arts."

In my humble opinion, Congress speaking directly on the issue of patentable subject matter within the United States is an often overlooked but essentially important component of international intellectual property protection and enforcement. It is not the role of the Courts to make these determinations. However without further direction from Congress, the Courts are forced to determine the appropriate balance for the grant of these limited government monopolies.

Conclusion

International intellectual property is very important to this nation. For the United States to maintain our leadership in the global economy, Congress, the Courts, and the Administration must remain ever vigilant nationally and internationally for the good not only of the people of the United States but also for the benefit of the citizens of the world. We all benefit from American technological advances. Intellectual property rights keep those advances coming.

I look forward to further action by Congress in evaluating the equities and determining the appropriate balance that meets the constitutional challenge of promoting the progress of science and the useful arts in a way that is effective for

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[12] Similarly, in the area of copyright, just last week, the Supreme Court granted certiorari on a copyright case addressing the "first sale doctrine."[12] This is the second time in less than two years that the Supreme Court has examined this issue of whether legally obtained foreign copies of copyrighted materials may be legally imported and sold within the United States without infringing United States copyrights. Copyright owners already believed this to be settled law; however, there is a split among the circuits and in this case it is very possible that bad facts may result in bad law. The result could possibly narrow copyright and patent holders' rights.

the needs of technology and the progress of culture and human kind in the 21st Century. The "Steves" of the future are dependent upon it.

Thank you for this opportunity to present an academic view on these issues.

Mr. GOODLATTE. Dr. Sheppard, you have a unique perspective on that, and we appreciate your statement.

I will begin the questions with Dr. Waldron. Dr. Waldron, in the patent world, there are many hurdles that a foreign country can raise to prevent a company from selling a product based on a lawfully granted patent. But in recent years, we have seen countries like Brazil, Thailand, and India using the threat of a compulsory license as a negotiating strategy to force American companies to manufacture or license their products to local companies at government mandated prices. Recently, India took the unprecedented step of issuing a compulsory license against a Bayer oncology drug, stating among other reasons that the patented drug was not being sufficiently worked in India because it was not locally manufactured.

What steps can the U.S. Government take or should it have taken to ensure that countries think twice about using a compulsory license simply as a negotiating strategy or to facilitate their budget planning?

Mr. WALDRON. The U.S. Government should take a hard line on these issues. I think if you liken compulsory licensing to the lifeboats on an ocean liner, you don't frequently see those being employed except in extraordinary circumstances. In fact if they are used regularly, one would begin to question the sanity of running ocean liners, if that would be the only recourse. What we really need to do is get to the heart of why some of these countries are imposing compulsory licensing. Some of them are for fiscal reasons. They haven't put enough money in the budget for their health care systems. These are not extraordinary circumstances that would justify essentially the abrogation of an individual patent holder's rights. I mean, this has a direct effect if it were to continue and extrapolate to other countries. And other countries may mimic what has happened in Brazil and India and Thailand, which would be devastating to the U.S. industry. This has a direct effect on our ability to sell drugs in those countries and has a direct effect on the investment that we put into developing drugs that may be of use in those countries. And it has a direct effect on the jobs that are created in the United States. We have a competitive advantage versus the rest of the world in the biopharmaceutical and biotech area. We should not hesitate, as a government, to go forward and protect the interests of our companies, particularly our competitive advantage versus those in the economic area.

Mr. GOODLATTE. If the Indian Government's decision is not reversed on appeal, do you envision an increased risk for other patent protected drugs or even other patented technologies in other areas, like energy, communications, and the Internet basically being taken away by foreign governments?

I will ask you and then I will ask Mr. Israel the same question.

Mr. WALDRON. I believe there is a risk. This is something that is being experimented with. And I think it is also a test of our resolve to see whether we are going to stand up for our own industry in these contexts. If we don't send a hard message on these issues, I think we will find it increasingly difficult to combat it at a later stage when sort of the horse is out of the barn. I believe it is important to make a statement very early about this because we will find green technology and other industries under the same pressure.

And when we find the whole panoply of our industries under siege and unable to do business in these countries, I think we will find ourselves in a sorry state.

Mr. GOODLATTE. Thank you. Mr. Israel?

Mr. ISRAEL. I think the dynamic that you lay out, Mr. Chairman, is exactly correct. And I think we are seeing it play out in realtime. I think we have seen in recent years the threat of compulsory licensing being applied or at least discussed in relationship to clean technologies. I think we need to be also very aware that this isn't just an individual Nation concern but it is a more global concern because a lot of the countries that are using this tactic or threatening this tactic are also working very hard within global organizations, such as WIPO, the World Intellectual Property Organization, to promote this type of position, to promote this type of a framework. Brazil, for example, has recommended within the Standing Committee on Patents at WIPO that a manual be put together that would instruct countries on how to essentially work around intellectual property rights.

So as Dr. Waldron lays out, this is something that has a slippery slope dynamic to it. I think we are seeing it played out in realtime and I think on the compulsory licensing question, we need to be very focused on the prongs that exist within TRIPS that do allow for compulsory license. You need to exhaust the negotiations with the rights holders and there needs to be a true emergency at hand. And I think in very few—no circumstances really have we seen those prongs being met. And it has largely been used as a tool, either as a negotiating tactic or for other competitive purposes.

Mr. GOODLATTE. Dr. Waldron, the Administration is currently negotiating a Trans-Pacific Partnership Aagreement that includes provisions dealing directly with the issue of regulatory test data protection and how it should be protected.

Can you explain to the Committee the importance of data protection, the markets that lack adequate protection, and how it should be protected as a part of the TPP? And I will ask that question of Mr. Israel as well.

Mr. WALDRON. The 12 years of data protection that you mentioned that is set forth under U.S. law and we believe is key to being part of the TPP and other free trade agreement negotiations that are ongoing, the reason we say it is key is because the biomedical and biotechnology industries are extremely risky industries. The investment is very risky. There is an extremely high attrition rate. As I noted, it costs over $1 billion on average to develop a new drug. In these times of selective capital movement around the world, we want to ensure that companies feel certainty in investing in drugs so that when they come to a country or one of our trading partners that they are at least guaranteed a period of nonusage of their data in the regulatory scenarios. It is absolutely critical to have that certainty and I think that we would absolutely think it is a key part of any trade negotiation going forward.

Mr. GOODLATTE. Mr. Israel, my time has expired. But I am going to ask you one more question and you can address both. We know that many of these countries have de facto TRIPS violations. Should the United States be more aggressive in bringing cases at

the WTO or utilizing our other international trade tools? And also, can you give me a sense of what the Bush administration did?

Mr. ISRAEL. Certainly, Chairman Goodlatte. I think the answer is definitely. I think the position of the United States Government—and this transcends any Administration I think—should always be to enforce the interests and the rights of American companies and American intellectual property holders at the WTO through well constructed and winnable cases. It is a very difficult process, as you know. And you have to win these cases when you go forward with them. The Bush administration brought about 24 cases before the WTO and has expanded a number of fields and ranges. There were two cases brought for intellectual property infringements against the Chinese. We settled a patent case against the Argentineans in 2002. So there is an active history here, and I think the Obama administration is carrying forward with that.

In terms of TPP, just very quickly, as Dr. Waldron noted, it is very important to include provisions regarding data exclusivity within all of our trade agreements. I think it is important to understand that the proprietary test data that is required for regulatory approval of a pharmaceutical or a biological product is in and of itself an intellectual property. It is a piece of intellectual property. It is very difficult to construct that data. The Administration has stated that it is negotiating TPP as if trade promotion authority were in place, which unfortunately it is not. Trade promotion authority—and it dated back to the 2002 Trade Act which extended it to 2007—stipulates that the government, that the Administration, any Administration should negotiate a trade agreement that attempts to mirror or mimic U.S. law as closely as it possibly can. Of course in U.S. law, we do have 12 years of data exclusivity for biological products and 5 years for pharmaceutical products.

So I think that indicates a note of consistency that should be noted as we negotiate to TPP.

Mr. GOODLATTE. Thank you very much. My apology to our other two witnesses. I am sure that other Members will have some questions for you.

And I now yield to the Ranking Member, Mr. Watt.

Mr. WATT. Thank you, Mr. Chairman. Let me first compliment all four of the witnesses on your testimony which dealt very well with a description of the problem. But as I started to mention in my opening statement, I am more interested in flipping the switch and trying to find some solutions to the problem. I think we have identified the problem pretty comprehensively, and I know that is what this hearing was about. But it seems to me that Representative Waters and I may have a slightly different perspective on this because we serve on both the Financial Services Committee and the Judiciary Committee. And there seems to me to be three areas in which our economy can be pretty—either out of step with the rest of the world or in step with the rest of the world. And I think we probably have done a better job in the financial services economic currency area than we have in the trade policy area and the intellectual property area. Those are the three areas generally where I kind of look at this. One side of me says that it is easier, I suppose, to have a world regime of money because you are dealing with only one product. In fact, when we stepped outside of deal-

ing only with money and started dealing with derivatives and collateralized debt obligations and other things and we didn't have any worldwide system of dealing with them, our financial services system broke down, too, and our economy collapsed as a result of it.

So I am not here bragging about the financial services mechanisms. But at least we have you know Basel I, II, and III and the International Monetary Fund and what have you. I don't know that there is a parallel system of entities in place in the intellectual property area. And I am not sure we have done an outstanding job of writing into our trade policies any requirements that there be any harmonization of intellectual property standards. We tend to approach these things, it seems to me, in different categories, even though they intersect with each other regularly.

So I guess my general question would be, what are the incentives that would make other countries want to be more aggressive in the intellectual property area? How can we increase those incentives? Is the only way that we have to increase those incentives to increase the disincentives for them not to do it? In other words, a more punitive deterrence—what is the word I am looking for—reactive kind of system where we retaliate against people and other countries who don't do it. Is there some positive way we can incentivize this other than increasing the negative way we do it?

Those are the two questions generally that I—and I am sorry it took me so long to kind of outline my vision of how this works. But maybe my vision of how it works is inaccurate also. And if you want to take a shot at dealing with that vision, I am happy to have you do that, too. But I am more interested in finding out whether you think there are ways that we can incentivize other countries to have a more robust intellectual property protection regime rather than just retaliating against them for not doing it.

Mr. WALDRON. Thank you for that question. I do think that there are things that we can do. The U.S. economy is the prize of a lot of our trading partners. They want to do business here. We allow a number of countries and their businesses to do business in the United States. I think that there is a lot of levers that we can push on sort of ensuring that countries respect intellectual property, particularly our intellectual property, and come to a harmonized regime on intellectual property. It is like, right now we have several FTAs which sort of remain unenforced with respect to IP provisions, Chile being one of them where it has been pending for 7 or 8 years and still that country has not implemented measures to comply with its free trade agreement. I say that we should at least take a serious look at allowing other countries to have the benefits of trading with the United States, yet at the same time not enforcing their obligations reciprocally I think is problematic, and I think we have to take a serious look at that. I also think diplomatically—I mentioned the USPTO attaché's program is a positive step. I think we need to empower our Diplomatic Corps on IP issues, and I think that they can achieve good results locally if we are able to empower them to work essentially in the Diplomatic Corps to achieve those goals. Other countries around the world—I mean and there are many of them—have topnotch people pushing IP issues in a number of fora, and I think that we should actually look to

that as a mechanism for showing that we are serious about this and we are empowering people to do it and that we really mean it.

Mr. WATT. Let me go to the other end of the spectrum here because my time has run out with my question rather than your answer. We will get an academic perspective, and then at some point in the process later, maybe you can address, Mr. Israel, I am particularly interested in your perspective on it since you were in the prior Administration and had something to do with it. The Administration, I think, is consistently trying to find an answer to the mechanism here.

But let me get an academic perspective on it from Dr. Sheppard.

Ms. SHEPPARD. You mentioned the three areas, and that is a very important point. One of the reasons that TRIPS, Trade-Related Aspects of Intellectual Property, that agreement was seen to be such a success—and, frankly, countries thought it was very heavily favored toward industrial Nations, was because for the first time, it melded two of the areas that you talked about. It linked intellectual property with trade. And by doing that, they were able to have an active redress for countries that were in violation of IP.

Prior agreements, such as Paris and Berne, did not tie trade to intellectual property. By tying tade to IP, they were able to look at the interdependency between the countries because as was mentioned a moment ago, not only do we want to sell our products abroad and have them protected, they want to sell their products here. And by linking those two things together, trade and IP, if IP isn't respect on one end, then perhaps something that they want to sell here is not able to be sold. So that is how we link those two things.

TRIPS was successful on that basis. However, perhaps now we need TRIPS Plus, and that is what the TPP, some people believe and also ACTA are attempting to do. I am going to stop on that point.

Mr. MURPHY. Mr. Chairman, may I briefly add three observations.

The first thing I would offer up is the United States, as I said in my statement, can lead by example. One thing that we can do is ensure that we as a government are sending consistent messages to our trading partners. In some areas involving intellectual property, there are mixed signals. On the one hand, you have some of the trade agencies that are pushing very hard to ensure strong enforcement and strong protections.

There are other agencies whose missions are tangential or touches on intellectual property which may be saying things that are sending some of our trading partners the idea that maybe U.S. policy is shifting. Such as, for example, comments on certain high-profile patent litigation in the United States, which suggest an evolution in our law. Also, for example, the nexus between antitrust and intellectual property right now is in a state of change. Governments around the world are watching what emanates from Washington at the nexus of these two fields. Again, foreign governments are drawing conclusions, perhaps selectively, that what we are doing and talking about domestically is consistent with their own domestic interests.

Secondly, I agree with Dr. Sheppard that more can be done for TRIPS Plus obligations. As I said in my statement, I gave a list of different practices that are problematic to U.S. Patent holders which are not currently addressed by existing rules. There are loopholes, and there are certain exclusions or flexibilities which are being exploited, and I think we can do more to leverage what our foreign trading partners' economic interests are in order to shore up our own by getting better obligations.

Thirdly, I also note that a lot of developing economy companies are slowly moving up the value chain. Mr. Israel's testimony talks about the fact that Chinese patent holders are applying for patents in much larger volumes than ever before. It may take a generation or more, but I think we can be optimistic that some of our trading partners, who are causing us some difficulty, will slowly come to the conclusion that strong patent protection is in their own national interest.

Mr. QUAYLE. [Presiding.] Thank you, Mr. Watt.

The Chair now recognizes the gentleman from Ohio, Mr. Chabot, for 5 minutes.

Mr. CHABOT. Thank you. I would like to personally thank you for being generous with your time and for allowing me to go next. I had planned on attending a classified cybersecurity briefing at 11, so I am going to catch the tail end of it. I wouldn't have made it at all except for your willingness to allow me to go next. Thank you.

Mr. Israel, I have a couple of questions for you. In your testimony, you mentioned the current negotiations to establish the TPP, which could provide global patent protection for U.S. businesses. Again, in regard to the data exclusivity, and I know that Dr. Waldron has already commented on this somewhat, but if you can expound upon a little bit about why it is so important, so critical that we continue to negotiate for 12 years of data exclusivity?

Mr. ISRAEL. Thank you, Mr. Chabot.

I think the principle is so important, and Dr. Waldron did begin to explain why it is so critical for U.S. pharmaceutical and biotech and agricultural companies as they invest so much money in the regulatory approval process. I think the step of getting a patent granted in many of these countries is a very difficult and lengthy and expensive one in and of itself. You are then asked, obviously, to go to the regulatory agency and get that product approved and demonstrate its safety and efficacy. That is what this package of information that we are talking about really represents in providing an exclusivity so it cannot be relied upon by other competitors which have not put that similar set of resources and time and energy into constructing that information and providing it is absolutely critical.

As we have noted, the standard here in the United States is 12 years for biological products, 5 years for small molecule pharmaceutical products. So I think that the notion that we would be absolutely consistent and very strong on that consistency as we negotiate with our foreign trade partners, whether it is within the context of the TPP or other trade agreements, it is a principle in almost all of our free trade agreements. And certainly it is something that we need to be very vigilant to continue to stress going forward.

Mr. CHABOT. Thank you.

Can you tell us how the Obama administration has approached the data exclusivity issue as well as the intellectual property rights generally in their negotiations thus far?

Mr. ISRAEL. I can do my best to answer that question, Congressman. I am obviously not involved in a lot of the very important and well-structured arguments and negotiations that the Administration is leading. It is a very, very talented and effective team that exists at USTR. Victoria Espinel is obviously doing a great job leading the enforcement effort within the Administration. It is a difficult issue.

I think it is important to recognize, as we were engaged in this issue in 2005 and through the remainder of that decade, a lot of these issues were really just starting to kind of bubble up. India only put its patent law in place in 2005. China only joined the WTO in 2000. So they were really starting to heat up at that point. I think they are really starting to almost boil over at this point.

It is a difficult challenge, I think, maintaining the posture that the United States be as aggressive as possible to protect the economic interests of U.S. rights holders overseas, particularly in light of the fact that the United States has implemented the AIA and it has really set the global standard is an important principle for the entire U.S. Government. I think this is an issue that involves Congress and the Administration and industry, and everyone really needs to be focused in working together. So I think we need to all accept that responsibility and shoulder it.

Mr. CHABOT. Thank you. You mentioned that during your time with the Bush administration, the USPTO engaged with foreign trade partners to increase capacity and quality of patent prosecutions overseas. Under the Obama administration, have you seen a continuation of those efforts? How would you describe them?

Mr. ISRAEL. Yes, I think there has been a consistency and continuation. The PTO attaché program continues to be a very strong point. It is something which provides the U.S. Government a lot of information and relationship building with critical foreign governments, and provides U.S. companies access to expertise in countries and relationships. I know that Director Kappos has been very active in engaging other patent offices and trying to provide training in capacity building. That is one key area.

It reflects back a bit to the question that Ranking Member Watt asked earlier, where are the carrots, and where are the sticks? This is a carrot. I think the extent to which the United States, through the PTO and through other resources, can provide training and capacity, building to foreign patent offices that are struggling, obviously.

And I think we see examples in our judiciary as well. Judge Rader, the Chief Judge of the Federal Circuit, is taking the entire Federal Circuit, all of his colleagues, to China in May to interact with their colleagues in China and really try to build some capacity there.

So I think there are some carrots, and there are some sticks, and I think we need to deploy all of them sensibly.

Mr. CHABOT. Thank you.

I see my time has expired. I yield back, Mr. Chairman.

Mr. WALDRON. If I may briefly supplement the comment Mr. Israel made, regarding the TPP, the Administration has not yet tabled the 12 years of biological data exclusivity. I think, given the breadth and the scope of this agreement and the effect on jobs and our economy going forward in the future, I think it is imperative that we look toward tabling that as soon as possible.

Mr. GOODLATTE. [Presiding.] The gentlewoman from California, Ms. Chu, is recognized for 5 minutes.

Ms. CHU. Thank you, Mr. Chair.

Dr. Waldron, the U.S.-Korea trade agreement did provide state-of-the-art commitments in intellectual property rights. Can you discuss whether you think trade agreements that incorporate these strong IP protections, like the U.S.-Korea free trade agreement, are ones that the U.S. should be seeking, and do they help or hinder your industry in foreign markets?

Mr. WALDRON. We believe that the Korea-U.S. Trade Agreement is sort of the gold standard and, along with adding in a provision for 12 years of biological data exclusivity, would be the gold standard going forward for free trade agreements. I think that is the underpinning of showing how serious we are about IP protection with our trading partners. I think they are critical in their implementation, and I think they have been very effective in some countries but not all countries, and I think we have to be willing to enforce those agreements and make sure our trading partners abide by them going forward. And I think they are very beneficial in the long term if they have these provisions in them for IP protection.

Ms. CHU. Okay. Dr. Sheppard, as you know, the Special 301 Report is an annual review of the global state of intellectual property rights protection and enforcement, which is conducted by the Office of the United States Trade Representative. It identifies a wide range of serious concerns and lists the countries which are deemed to have inadequate intellectual property right protections. What is the significance of this report and how can it be used to incentivize countries to harmonize their laws to conform to these international agreements to which they are a party?

Ms. SHEPPARD. I thank you for that question.

As I noted in my testimony, there are some countries who have been on the list and then have put through the necessary changes to get off the list. But there are many, many more countries that have been on the list, the watch list, the priority watch list since the inception and are still there today.

Does that mean that the list is not important? No, that is not what that means. The list is very important because it requires the Administration to look every year at the agreements and at individual countries to figure out who is in compliance and who is not, either de facto or in its result, and then have a country-level conversation on specific issues. In some places, changes have been made. In the Special 301, they also make a determination on whether or not they are going to go before the dispute settlement board at the WTO, and that is an important determination. Unfortunately, or maybe fortunately for some, that particular avenue has not been taken up as often as it could be. That is one of the sticks that is available.

But I believe your question is, is 301 important? Yes, because it shines a spotlight on the issue, and action plans are developed.

Last year, the Administration started to have the actions plans, invite countries to work with the Administration to develop an action plan that the other countries believed they could implement. I don't know how that process is working. It is still the first year; but this is the first year where the Special 301 and the Administration have reached out to the other countries to make sure that the action plan is something that is doable in the eyes of the other country.

Ms. CHU. Some countries that were on the 301 listing were eventually removed from the list. In fact, I think South Korea and the Bahamas have succeeded in removing themselves from this list. How did they go about doing this?

Ms. SHEPPARD. I don't know the exact details. Perhaps Mr. Israel knows the exact details. But there is an action plan. There are things that listed that say in order to be in compliance, you need to do A, B and C. And without knowing the details, they must have complied with at least the majority of those issues.

Mr. CHU. Mr. Israel?

Mr. ISRAEL. I would have to check some of the detail. I would suspect that their implementation of the Free Trade Agreement that the United States agreed to with South Korea probably has a very significant impact on their being removed from the list, and they implemented some things such as the TRIPS Plus provisions that we negotiated with them as part of that free trade agreement. And so I suspect that put them on the path to making some pretty significant improvements.

Ms. CHU. Although I don't think the Bahamas has a free trade agreement, so how did they end up getting removed from the list? The Bahamas?

Mr. ISRAEL. That I am not sure of, Congresswoman. I would have to check and probably get back.

Ms. CHU. Dr. Sheppard, how is it that a country could be part of the TRIP agreement but still be seriously having deficiencies in protecting intellectual property rights?

Ms. SHEPPARD. The TRIPS agreement, like most international agreements, it is just an agreement. I believe it was Ranking Member Watt who alluded to before—we can give our input, but we can't make anyone do anything. And conversely, they can have their input, but they can't make us do anything. These agreements are gentlemen's agreements that you are going to comply with what your word is. If you don't comply with what your word is, then we will put higher tariffs on some other product.

As I mentioned earlier, the United States has not taken advantage of that as often as possibly it could. But there are countries, including the United States, which are in violation of the TRIPS agreement.

So, in my opinion, it is hard. It is hard when we are still in violation on some issues and go to other countries and talk about them being in violation of their issues.

Ms. CHU. Thank you.

Mr. MURPHY. Mr. Chairman, may I briefly offer an observation based upon my time at USTR?

Mr. GOODLATTE. Sure.

Mr. MURPHY. Thank you very much.

Congresswoman Chu, I agree with your question or statement that Special 301 and the annual reporting and watch list is still very valuable. It continues to create an opportunity for peer pressure and observation, for lack of a better term.

But I can also offer this: Special 301 predates the creation of the WTO and the TRIPS agreement. The United States as a member of the WTO is constrained in its ability to bring pressure to bear against trading partners that are not in compliance with their TRIPS obligations or otherwise maintaining policies that burden U.S. IP holders. I think we need to have a very honest conversation about how in the post-WTO, post-TRIP world, can we ensure that our trade enforcement agencies have some leverage to bring to bear that does not itself cause the United States to violate its own trade commitments, in order to focus the attention of our foreign trading partners on doing what they need to do to better protect U.S. IP.

Ms. CHU. Thank you.

I yield back.

Mr. GOODLATTE. Thank you.

The Chair recognizes the gentleman from Arizona, the Vice-Chairman of the Subcommittee, Mr. Quayle, for 5 minutes.

Mr. QUAYLE. Thank you, Mr. Chairman.

And thank you for holding this important hearing today to examine the challenges to U.S. intellectual property protections in foreign countries.

As others have noted, the U.S. Commerce Department reported earlier this month that intellectual property supports 40 million U.S. jobs, or 28 percent of our workforce, and contributes over $5 trillion to our GDP. According to the report, intellectual property protections have a direct and significant impact on the U.S. economy, and the jobs it creates are high-paying and important for working families. This really shows how important this hearing is, and I thank all of the witnesses for their testimony.

Dr. Waldron, you mentioned Chile as not enforcing IP protections as a part of the FTA. I was wondering if you could provide a few additional examples of lack of enforcement of basic patent rights abroad and explain how that lack of enforcement really hampers the innovative industry's ability to maintain and grow jobs here in the United States?

Mr. WALDRON. There are a number of provisions, as I look at the countries for which we have free trade agreements, but Chile is an important one because I think it is one where it is imperative that we have sort of a linkage system which would be set up to protect our IP rights before the market essentially is destroyed by the entry of competitors that essentially can go on, and the enforcement mechanisms are very poor. If you are not able to export to a market—I mean, there are markets in Latin America where we have introduced a product, and within 1 year, we have lost 85 percent of our market to 23 competitors. That was Lipitor.

With Viagra, there was a case where we lost 98 percent of our market within a year to 35 competitors. So there is no shortage of competitors willing to come in, particularly in an instance where you are not getting the patent protection that you have applied for.

There is no data exclusivity protection. So, within a very short period of time, within a year, competitors enter the market. And there is no linkage mechanism, no means to resolve a patent dispute, if you have a patent, within that period of time, as we do in the United States.

These markets represent huge growth opportunities for U.S. businesses. They are big. If we are regularly losing 90 percent of our market to local competitors that is a problem because we can't expand locally at home, we can't invest and make the investments and create the jobs at home that support those innovative industries, and it is just sort of a chain reaction of things that sort of piecemeal around the world add up to a collective problem for the United States where we have that competitive advantage.

Mr. QUAYLE. Do you think that the Administration is doing everything that it can to support U.S. industry and enforcing their rights?

Mr. WALDRON. I think we really need to ensure that if we have free trade agreements with partners—and Chile has been noted—I mean, there are others—that we make sure and follow-up on that. There is the 301 mechanism, but it seems to be a paper tiger sometimes. It seems it is not followed up on, or it is a chastisement, but it really doesn't have any strong economic teeth. I think there really has to be something here that sort of makes it perfectly clear that these kinds of violations are backsliding on obligations, and that is unacceptable.

Mr. QUAYLE. Thank you.

Mr. Israel, what additional steps can the U.S. take to improve judicial education in foreign countries so that enforcement measures can be counted on?

Mr. ISRAEL. I think that is a key question, Congressman.

And It does, again, kind of touch on this theme of, what can we do to provide incentives, and where does the United States have leverage that doesn't necessarily implicate direct trade rules or bringing cases? There have been I think some great examples in the past where the Justice Department, for example, has sent delegations to places like India to help train judges, to work with their judicial system, and to try to give them a little more capacity on what are obviously very complicated cases in any country. We work directly with China. We had a system in place called the case referral mechanism with China for several years, whereby American companies could work directly with the Commerce Department and PTO and our attaché program in China, and have really kind of a pipeline directly into the Chinese enforcement officials to refer specific cases of infringement that they saw on the ground.

I noted the efforts of some individual jurists, such as Judge Rader, who has been very active in this area. But I think we need to look at this as one of those kind of compliant/noncompliant areas, where we see some obvious and overt areas where countries violate TRIPS, as Dr. Sheppard has noted. But there are a lot of areas that when you get on the ground, if you are an American company and it takes you 10 years to even get a patent, and then when you get it, there is a judicial system that simply disallows you, through inconsistency or inability, to really enforce that patent, you are dealt a hand that you really can't compete with.

Mr. QUAYLE. Do you think even with the education aspect, where the DOJ is going in and educating judges, do you think you are witnessing, even if you do educate and get them up to speed on patent protections and patent law, that if you have a process or a thought process from the governing body, that they are just not going to actually administer or protect patent rights from out-of-state companies, then it is really not going to do that much?

Mr. ISRAEL. Good point. A very fair point. I think you see some things that cut against those best efforts very dramatically. It is not uncommon in China, for example, in high profile intellectual property cases for officials of the Chinese government to physically be present at those hearings where there is a state-owned enterprise potentially implicated in the hearing. It is very hard to counter that from the United States. I suppose we could have our diplomats attend a range of cases in big countries like China, but you are up against not just some systemic flaws but, as you know, you are clearly up against some attempts to tilt the competitive framework, again the foreign rights holder, typically the United States.

Mr. QUAYLE. Thank you, I yield back.

Mr. GOODLATTE. I thank the gentleman.

The gentlewoman from California, Ms. Waters, is recognized for 5 minutes.

Ms. WATERS. Thank you very much, Mr. Chairman.

I had to step out for awhile and I can imagine that some of my questions may have already been answered. I will try to frame them in a way that could glean some additional information.

The first thing I want to know is what is our Trade Representative doing on these issues? That is where we place responsibility for ensuring that we have fair trade, and I am sure this must be an issue with the Trade Representative.

Dr. Waldron, what is our Trade Representative doing?

Mr. WALDRON. I don't have the exact details of the procedures going on at USTR right now, but I do know that they have not tabled 12 years of biological data exclusivity yet in the Trans-Pacific Partnership negotiations that are ongoing. I think it is very important for us to ensure that there is a strong IP package in this. I think that is an essential part of it, and it has not yet been tabled. And I think we really have to ensure that we do this because of the breadth and the scope of this agreement. I mean, it involves a vast chunk of the Pacific Rim countries. These are huge markets for all of American businesses, and I think we have to get this right because it is going to have huge knock-on effects later.

I don't know why there has been delay in introducing this; but certainly, it is something that represents U.S. law, and I think we should definitely push the Trade Representative.

Ms. WATERS. Dr. Sheppard, has this risen as an issue with the WTO? Have we taken any initiative from the United States to look as if, if not actually, make this an issue with the WTO?

Ms. SHEPPARD. Yes. The United States and the USTR has taken up several issues with the dispute settlement body. The issue went directly against China, and the United States received a lot of negative reaction from China for taking them to the dispute resolution settlement board. But the conversations between USTR and the

United States had no fruitful outcomes. And when that happens, that is the process you are able to go through.

Someone mentioned earlier, I think it was Mr. Israel, talked about the other times when the United States has tried to negotiate, negotiate, and then gotten nowhere. That is why I think the Trans-Pacific Partnership, as Dr. Waldron was talking about, and other avenues of TRIPS Plus agreements are so important. And that is one of the things that the USTR is doing right now, actively negotiating new treaties that will put into place some of the lessons learned from what was lacking in TRIPS.

TRIPS was a huge step forward, but it has been 18 years since then. And in that time, other industries have grown up that weren't envisioned then. So new protections and new laws need to be in written. Mr. Murphy can talk about this, having been at the USTR, more than I can—I haven't been there—that they are actively every day pushing forward our policies in every country. We just don't hear about them.

Ms. WATERS. Well, you know, what you are describing has been going on for an awful long time. And it seems to me it is time for a resolution.

Mr. Watt alluded to the work that we have done in financial reform. Tremendous work with Dodd-Frank and all that goes along with that. So having taken a look at what you are describing and the negotiations that have gone on and the continued and long-term bias against us in many ways, what do you recommend can be done legislatively outside of the USTR Trade Representative working for us?

What do you recommend, Mr. Israel?

Mr. ISRAEL. That is a great and obvious question, Congresswoman Waters.

Trade promotion authority, giving that to the Administration, from the standpoint of empowering their negotiating status, would be a good thing. I think there are things that we can do. There are obviously resource issues which are difficult to discuss and it is a very difficult environment for that. But I think things like potentially giving the Patent and Trademark Office greater ability to leverage and manage the IP attaché program overseas. Right now, it is a bit complicated as they work internationally. It is not their natural, kind of organic statute to place individuals and diplomats in embassies. And so I think there are some things we could do that might strengthen that program and empower it even more.

Ms. WATERS. Excuse me a moment. You just said something. I have never heard that the role that our ambassadors and their staffs could play is to take an issue like this in country and help to promote the idea of fairness and a level playing field. That may be something, Mr. Watt, that we may be able to encourage in some ways.

My husband was an ambassador, and they talked about a lot of things. Of course, he told me that there were a lot of things that he couldn't talk about. But I never heard that this was a role that they played, even though they have one of their designated staff persons dealing with economic development or something like that in these countries. I have never heard them talk about this.

Please continue. Thank you.

Mr. ISRAEL. Clearly, the global footprint that the U.S. has through its embassies and diplomats overseas is huge. I personally think this problem, this issue, is equal parts law and diplomacy; getting the legal framework correct, enforcing TRIPS, all of the very detailed things that Dr. Sheppard noted is huge. But there is a diplomatic element to this as well. We need to be working very aggressively with our trading partners that we are aligned with on this issue—the Europeans, the Japanese, and other developed countries.

I think one of the things it is, again going back to this carrot and stick formulation that the Congressman Watt spoke about, a lot of countries, particularly the growing BRIC countries, China in particular, I think are very sensitive to being as framed outside the norm. They may be more sensitive to that than a handful of individual WTO cases. If their legal system is portrayed consistently and effectively as being outside the global norm by their trading partners, by the United States, the Europeans, their partners that matter, that has an impact.

I think, to your point, if you have an ambassador and a team in country that are focused on this—Ambassador Rant from 2001 to 2008 had a series of annual IP conferences in Beijing. The vice premier of China frequently attended, and Cabinet members from the United States frequently attended it. It really became a focal point for driving these issues.

Action-forcing events are key. They force our government to put things on the table. They force the other government to react to those. So there is a lot of diplomacy that can be done around this issue in a very strategic way.

Ms. WATERS. Thank you very much.

Our Chair has been very generous with the time, but in wrapping up, do you see this as something that can be framed as a serious trade imbalance issue, and how do we do that?

Mr. ISRAEL. I think it is absolutely a serious trade imbalance issue. I think we need to look at this issue when we view overall American competitiveness in the same way we talk about making our tax system competitive, making our regulatory system competitive, our R&D portfolio, all of these things that, at a very high level, feed into issues that are of the level of congressional committees and Cabinet officials and CEOs. I think this is an issue that deserves a place and attention on that list as well.

Mr. WATT. Mr. Chairman, may I make a one-sentence intervention?

Mr. GOODLATTE. The gentleman is recognized.

Mr. WATT. I just remind my colleague from Financial Services that it took a worldwide economic meltdown to create the environment for international harmonization in the financial services area. I am not sure that those kinds of incentives are there yet in the intellectual property protection environment. So I kind of stacked the question a little bit, but I didn't want anybody—we got a lot more cooperation internationally after the meltdown than we were getting before the meltdown.

Mr. MURPHY. May I respond briefly to Mr. Watt?

Mr. GOODLATTE. Briefly.

Mr. MURPHY. Innovation and patents are key to our 21st century economy. We need a corresponding trade policy that recognizes that. We need to find better tools and levers for our trade negotiators and our diplomats worldwide. We need to have strategies that focus on foreign capitals as well as the foreign delegations at international institutions. We often have disconnects between governments, our foreign trade partners in different locations.

Mr. GOODLATTE. Thank you, Mr. Murphy.

The gentleman from Georgia, Mr. Johnson, is recognized for 5 minutes.

Mr. JOHNSON. Thank you, Mr. Chairman.

This is a very important hearing today. It comes at a great time. Today is World IP Day, where we celebrate. Everyone goes home for half a day, and we celebrate innovation throughout the world and put up lights and everything and give gifts. It is a wonderful day. We are all working today.

The process and results of research, innovation and development, and the protection of these results through our patent, trademark and copyright laws are very important, particularly in a global community. There are major patent barriers that American patent holders face in protecting their intellectual property while doing business in many places, including China.

Dr. Waldron, I know that you were asked a question earlier about the performance of the Obama administration and you mentioned that there was something that needed to be done before it expires. What was that?

Mr. WALDRON. It was getting the 12 years of biological data exclusivity into the TPP negotiations, the Trans-Pacific Partnership.

Mr. JOHNSON. Well, I tell you, we have had so much gridlock around here. Partisan politics have been the practice. It has resulted in us not being able to do many of the things that the country needs to do. But I am hopeful we will be able to get through this period, and with folks like PhRMA, I hope you will support good government and not gridlock government, and we can get these things—we can do the things that America needs to do in order to maintain its position in the global economy.

Now, I know that WTO members are required to make patents available for inventions in all fields of technology, but many countries discriminate based on the place of invention, the field of technology or whether products are imported or locally produced. Does China utilize regulatory and administrative hurdles to devalue patent rights of American companies, in your opinion, Dr. Waldron?

Mr. WALDRON. There are a number of levers that effect us in China. And I think when you talk about the patent grant process, we have a system of fairly arbitrary standards that are imposed that we have experienced as pharmaceutical companies on how much data is required to get a grant of a patent or a grant of a claim. It seems to vary considerably across the board. We think that they need to harmonize their standards better so it doesn't appear as arbitrary. It seems that we have a great deal of difficulty getting scope of claims in our patents that are broad enough to protect our products, and this is an important issue going forward.

The other issues in China range from enforcement of intellectual property, particular patents. The evidentiary hurdles are great. Of-

tentimes, foreign evidence is not allowed. Evidence has to be generated within China. Sometimes this is very difficult if you are trying to present a test result and there is nobody in China that can perform it; sometimes you are just out of luck. This is an unfortunate situation we face on a daily basis.

Mr. JOHNSON. If I might stop you right there, I wish I could let you go forward, but I have got one more question. I have more questions actually that I want to ask, but thank you.

Professor Sheppard, in China, do American innovators have sufficient recourse in the Chinese judicial system to protect their locally manufactured or their locally granted patents? And if not, tell us the extent of the problem and perhaps some solution for being able to solve?

Ms. SHEPPARD. The biggest part of the problem, and it is hard for us as Americans to really internalize this, is that there is no judicial independence in China. The courts are very much influenced by politics and the needs of the people. If putting a company out of business that employs 500 people because they are infringing is the right thing to do legally, a lot of judges won't do it because of political reasons. I don't know how we change that.

As we discussed earlier, Judge Rader goes to China on a regular basis and he is taking the entire Federal Circuit to talk about these issues. Maybe one of the things that we should be pushing for that kind of comes in from a different angle in protecting American interests is looking for not only democracy across the world but also judicial independence across the world.

Mr. JOHNSON. Anyone have any other comments about that?

Mr. ISRAEL. I think Dr. Sheppard hit it right on the head. I think it is a rule of law question as much as anything in China. China, except laws and rules they want to enforce, by and large doesn't enforce a lot of its laws particularly well. So I think you are dealing with a question of—there is a question of judicial independence. There is a question of the laws being relatively new in China. China only became a WTO member in 2000. So as a body of law, it is relatively new in China. I think it is, as Dr. Sheppard noted, it is almost first and foremost tied to economic rationales or social rationales largely in China, and that has to be a very difficult dynamic for any American company to walk into a courtroom and not just be confronted with needing to win the legal argument, but also needing to win the social and potentially the economic argument against what they are faced in China in that courtroom.

Mr. GOODLATTE. Without objection, the gentleman is recognized for 1 additional minute.

Mr. JOHNSON. Thank you, Mr. Chairman.

Do you think that the way that—well, the Chinese economy in 2015 it is projected, 2016 maybe, is projected to become the world's largest economy. So that is something you have to deal with, America as well as all of the other countries and their economies in this global economy, and if the big, 800-pound gorilla is cheating, how do you stop the cheating? Is it through a trade war? What do you do in order to encourage compliance with international standards in a situation like this?

Mr. ISRAEL. I think it has to be a mix of tactics. I think it has to be a mix of very high level focus by the U.S. Government and

other governments that are similarly impacted. It needs to be a head of state issue. I think it consistently has been for the United States for several years. I think we need to make—look at ways to make improvements to the Chinese judicial system.

Mr. JOHNSON. Do the Chinese want to do that?

Mr. GOODLATTE. The time of the gentleman has expired.

The gentlewoman from Texas, Ms. Jackson Lee, is recognized for 5 minutes.

Ms. JACKSON LEE. Let me thank the Chairman and the Ranking Member for this hearing, and the Ranking Member of the full Committee who studiously attends these hearings to build his excellent portfolio of knowledge, Mr. Conyers. I am delighted that he is here and an active Member of this Committee, among others.

Let me acknowledge, standing behind me but not in the room, Mr. Chairman, Amanda Woodson, who is my daughter for the day, a beautiful, young 13-year-old, who is learning about protecting our assets. As a 12-year Member formerly of the Science Committee and now a Member of the Homeland Security Committee, I have always believed that science, technology, the work that many of you are doing, is the work of the 21st century, 22nd century, and it is a job creator. Which makes me even more proud to welcome back Dr. Christal Sheppard, who quietly served us and did not acknowledge the genius of having a masters and a Ph.D. in cellular and molecular biology. I needed to put that on the record. So I know the University of Nebraska School of Law is excited that we added a smidgeon to her vast talent. We are delighted to see her as a witness.

I would like to take a different approach, and again, let me say that I couldn't be more chauvinistic, and I don't usually use that word, on the inventiveness and the level of technological sophistication that America has. And we need to protect it.

So, first of all, I want to acknowledge that President Obama has elevated to Cabinet status the Intellectual Property Enforcement Coordinator, and I want to have our representative, Dr. Waldron, comment on that elevation and how that can be utilized?

I would like Dr. Sheppard to answer a question that I will read in just a moment, but let me raise a question generally to ask about intellectual property jobs and trade agreements and the importance in putting in strong provisions. If you can take that question down.

But what I really want to talk about, because I met with members of the Chinese embassy yesterday, and I truly believe that we have an opportunity to be a friend and that we are doing business with China. They want to do business with us, and they are looking to be able to frame their structure going forward in a way that comports with the respect of the intellectual property of those who they engage with. So I am very interested in doing it this way, and that is the moving and looking at the Leahy-Smith bill, and I am looking at that, that deals with reestablishing a patent system for the global market. What I would like to see us do is for America to be the standard for all countries, and if you are not in keeping with America's standard, you are outside of the marketplace in both world ideas and world opportunities.

Dr. Waldron, would you proceed with that.

And Dr. Sheppard, I think you heard my question. Why don't we push getting our standards to be the world standards and match it with enforcement, and anybody that is outside of that circle simply can't do business? Because everybody recognizes what is precious, and that is your genius and the idea of Bayer aspirin being manipulated would not hold because that country would be isolated because no one would dare go there if their procedures undermine the process. Would you go forward on that answer?

Mr. Israel, you might answer, too, since you are formerly head of that agency.

Yes, Dr. Waldron.

Mr. WALDRON. I agree with you wholeheartedly, Representative Jackson Lee. The genius of America is its innovativeness. And our competitive advantage vis-à-vis other countries is our prize asset, and we should have as a matter of policy a means of protecting these things, the things that we develop and the things that we market and sell abroad.

We acknowledge the elevation of the IP coordinator status within the Obama administration. This is a welcomed development. It brings IP to a high status within the Administration, and we think that is a good thing to have on people's minds. It also deals with the issue of counterfeits, which is something that is a pernicious danger that we also have to be constantly vigilant about.

But we do need a set of policies in this government that sort of protects American innovation and American business abroad. As mentioned earlier in some of the discussions, the diplomatic emphasis here is essential to having that go forward. So I agree with everything that has been said.

Ms. JACKSON LEE. Chairman, can we allow them to answer the question?

Mr. Israel, would you add to your answer what strong provision we would need to protect, what kind of strong provisions?

And then I would like Dr. Sheppard to finish.

Mr. GOODLATTE. Briefly, if you would.

Ms. JACKSON LEE. Thank you, Mr. Chairman.

Mr. ISRAEL. Very briefly, I think the answer to your question partially answers the question that Congressman Johnson answered, which is regarding the Chinese and the economy.

Ms. JACKSON LEE. The answer to Jackson Lee's question partly is the answer to Congressman Johnson's question? I am not sure who you are answering.

Mr. ISRAEL. I am sorry, Congresswoman. Mr. Johnson asked a question.

Ms. JACKSON LEE. And I am asking a global question. I am not pointing to the Chinese. Thank you.

Mr. ISRAEL. Thank you. As China, in particular, becomes the world's largest economy, I think it is impossible for them to also have a judicial system simultaneously that is not taken seriously by the rest of the world. So I do think to your question, there is pressure that will mount. And I agree, they will gradually need to face that pressure and do something about it. And I do think that will have a very positive impact going forward.

Ms. JACKSON LEE. Thank you.

Dr. Sheppard, welcome.

Ms. SHEPPARD. Thank you.

The importance of taking strong positions in IP, very briefly, it is very essentially important. It is the only way that dollars come back into the United States. To use Apple as an example, iPads are made by a Taiwanese company with Chinese workers in China. The way that the money comes back to the United States is through intellectual property. And unless we continue and maintain strong IP, the inventiveness of our inventors and the R&D that we do here will never see returns from those countries.

As you mentioned, we do have leverage. They want access to our market; we want access to their markets. America is a really good market still. So we have leverage, and we shouldn't be afraid to use that leverage. It is part law, and it is part diplomacy, but we cannot afford to be a paper tiger, as someone mentioned earlier.

Ms. JACKSON LEE. Mr. Chairman, I would like to submit additional questions for the record.

And may I just indicate that I am very proud that one of my questions to be submitted into the record was written by Ashley Hawks who is my Texas Tech intern. This is her last week, and I wanted to congratulate her for the work she has done on behalf of the people of this country and the 18th Congressional District.

I thank you, Mr. Chairman. And I ask unanimous consent that my questions may be submitted in writing for a response.

Mr. GOODLATTE. We will cover that right now. I am proud of Ashley and her good work for you.

I would like to thank all of our witnesses for their testimony today.

Without objection, all Members will have 5 legislative days to submit to the Chair additional written questions to the witnesses which we will forward and ask the witnesses to respond as promptly as they can so that their answers may be made a part of the record.

Without objection, all Members will have 5 legislative days to submit any additional materials for inclusion in the record.

With that, I again thank our witnesses and the Members who participated, and this hearing is adjourned.

[Whereupon, at 12:02 p.m., the Subcommittee was adjourned.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING RECORD

Prepared Statement of the Honorable John Conyers, Jr., a Representative in Congress from the State of Michigan, Ranking Member, Committee on the Judiciary, and Member, Subcommittee on Intellectual Property, Competition, and the Internet

Today's hearing provides an opportunity for us to scrutinize whether the patent systems in foreign countries provide adequate and effective patent protection for American innovators and whether they provide a level playing field for American creators.

In particular, we should focus on the problems that American companies encounter when they request, enforce, and implement patents overseas.

And, I intend to explore in detail ways that Congress can foster U.S. global competitiveness with respect to patent laws and government policies in light of the recent enactment of the Leahy-Smith, America Invents Act.

There are several factors we should keep in mind as we consider this and other issues today.

First, a robust patent system is integral to the health of our Nation's economy.

Coincidently, today is World Intellectual Property Day, which recognizes the significance of preserving intellectual property protection for American businesses and inventors when they use international patent laws.

Last month, the U.S. Department of Commerce released a report finding that America's most IP-intensive industries in 2010 generated direct employment of 27.1 million jobs and an additional 12.9 million jobs. In 2010, these IP-intensive industries accounted for an estimated 34.8 percent of U.S. gross domestic product.

At its heart, intellectual property defends the economic value of the fruits of the mind's labor, whether it be the spark of invention or the inspiration of the artist. It gives an inventor or artist the opportunity to profit from their work, in order to both reward and support additional creativity.

It is imperative that American industry abroad is protected by sufficient international patent laws and government policies.

Second, it is critical for us to address barriers to effective international patent protection.

American innovators, industries, and other interested parties have identified many of these barriers as part of their proposals to the U.S. Trade Representative (USTR), as part of the annual "Special 301" review process.

Congress enacted Special 301 pursuant to the 1988 Trade and Competitiveness Act. The USTR produces an annual survey of the intellectual property laws of foreign countries and issues the "Special 301" report. Last year, 12 countries were included on the Priority Watch List and 28 were on the Watch list.

These submissions list challenges for international patent issues including lack of effective patent enforcement and administrative hurdles in the patent granting procedures.

Historically, the annual USTR Special 301 has mentioned the deficiencies in patent laws in countries listed on their priority watch list. Accordingly, I am looking

forward to reviewing the next Special 301 Report for 2012, which is due later this month.

Third, we must assure businesses that their patents will be granted within a reasonable period of time and not be discriminated against.

The patent application process, which includes patent filings, can often have long pendency times and prevent patentability for certain fields of technology.

While businesses need certainty that a patent will be granted in a timely manner, the total pendency for patent applications can be as long as 34 months.

In fact, applicants for pharmaceutical patents may take more than 5 years in many countries. For example, applicants for pharmaceutical patents in Chile have to wait an average of 8 years for final action on their patent applications.

Additionally, many foreign countries have barriers to effective enforcement. For example, China is often cited for their inadequate damages and ineffective injunctions.

Our trading partners need to live up to their international obligations and they should not discriminate against U.S. companies or fields of technology when it comes to patentability and market access.

Moreover, foreign governments should be able to condition approval of a U.S. innovator's license to patent technologies to domestic companies unless it reduces the price associated with the products.

This pressure from foreign governments is a demand for a reduction in the price of the patented technology, often below the global marketplace value.

It is clear that many foreign countries simply lack consistent stands for patentablity.

This hearing will allow us to explore these topics and determine what role Congress can play to promote a level playing field for international patent issues.

Response to Post-Hearing Questions from Chris Israel, Partner, American Continental Group (former U.S. Coordinator for International Intellectual Property Enforcement)

House Judiciary Subcommittee on Intellectual Property, Competition, and the Internet Hearing on "International Patent Issues: Promoting a Level Playing Field for American Industry Abroad"

Wednesday, May 09, 2012

Rep. Chabot- Questions for the record

Questions for Republican witness: **Chris Israel**

1.) The U.S. government has placed intellectual property attachés in embassies around the globe to help U.S. companies better protect their patent rights overseas. What are some of the things that the attachés are doing, or you think they could be doing to more effectively engage directly on behalf of American companies?

The US IP attaché program directed by USPTO is truly one of the most effective tools available to U.S. companies as they engage in the difficult and complex effort of protecting their intellectual property overseas.

I previously worked firsthand with our Attachés in several countries and have seen them offer in-depth and consistent support to companies that have issues ranging from general questions regarding gaining patent protection to sophisticated concerns involving foreign enforcement agencies. U.S. IP Attachés that have the background and contacts in their specific countries and regions can offer real-time help and let our trading partners know that the U.S. Government is vested in the proposition that American rights holders are treated fairly.

U.S. IP Attachés are also invaluable resources for all U.S. Government officials engaging on IP issues with a particular country. Again, during my time with the Bush Administration, I saw IP Attachés in China and India directly support Cabinet-level officials engaging in high-level economic dialogues, allowing them to speak with clarity and specificity and seek the most effective outcome for U.S. rights holders.

I believe there are several specific things that could be done to strengthen and support the USPTO's IP attaché program.

First, Congress should establish the IP Attaché program as an element of U.S. Foreign Service within the USPTO separate from other agencies within the Department of Commerce and the Department of State. This would free IP Attachés from the bureaucracy of these agencies and allow them to more aggressively pursue IP policy and enforcement priorities set by the Administration, Congress and industry.

Second, Congress should establish that IP Attachés may have the rank of First Secretary, Counselor or Minister Counselor. This seemingly minor adjustment makes a huge difference as Attachés operate overseas in terms of the access that it provides to more senior foreign government officials and within U.S. Embassies.

Also, USPTO should have sole discretion to hire, train and direct the U.S. IP Attachés. This will ensure that USPTO – the agency with by far the most expertise on IP issues - has the authority necessary to build the most effective IP Attaché program. USPTO has clearly demonstrated its capacity to successfully manage the program.

The Obama Administration should also make it clear that the primary responsibility of U.S. IP Attachés is to advocate on behalf of U.S. companies. This would remove any uncertainly in terms of the overall mission of the program and make it more effective. The objective of advocating directly for U.S. companies was a clear priority of the IP Attache program when it was launched in 2006. However, some companies have reported recently that when they have sought support regarding specific challenges to their IP rights, they have been told that Attachés could not advocate directly due to reasons unrelated to IP policy.

Finally, U.S. IP Attachés should be given the authority to work directly with governments in the countries they are based in to establish stronger partnerships and promote stronger IP systems in those countries which is an important focus of the program.

2.) To my knowledge, when it comes to intellectual property enforcement, it seems that certain foreign governments say one thing, but do entirely another. How can a country claim to be meeting their international obligations in the patent arena when U.S. companies are clearly finding a radically different situation on the ground? Are there any other steps that the U.S. government can take, or should be taking already, to fight these hostile practices which threaten U.S. companies, particularly in the Asian and Latin American markets?

This is frequently the reality faced by U.S. companies.

A recent case regarding True Religion Jeans provides a clear example in China. China has a set of trademark laws which technically meet international standards, but the reality facing True Religion is indeed "radically different". True Religion has applied for a Chinese trademark for the words "True Religion Brand Jeans" and "True Religion," but both applications have been rejected by the Chinese Trademark Office (CTMO) on the specious ground that the words are "detrimental to socialist morality." True Religion has appealed these decisions to the Trademark Review Appeal Board ("TRAB"), but despite being promised a decision in Summer 2011, the TRAB has yet to consider True Religion's appeals.

Both trademarks were submitted in English only – no Chinese translation or transliteration was provided as True Religion's global brand recognition is based on its English name.
When considering True Religion's trademark applications, CTMO intentionally translated the English phrase "True Religion" into "true organized cultish belief" in Chinese, even though the

CTMO has been made fully aware that the Chinese public uses the more accurate and benign translation of "true belief" when referring to the brand in the marketplace.

Based on this intentional mistranslation, the Chinese government continues to deny True Religion the primary tool it needs to enforce its intellectual property rights in China, even though Chinese authorities allow counterfeiters to manufacture and publically market knockoffs.

To address cases like this one, the U.S. must use all of its assets in a particular country. This includes direct engagement by the Embassy (in particular the IP Attache) and pressure from senior U.S. trade officials when they deal with their counterparts.

In addition, we should seek to re-energize the U.S.-China IPR Case Referral Mechanism that was launched in 2006 by the Bush Administration to facilitate the submission of individual U.S. company IPR cases through MOFCOM (China's Ministry of Commerce) to relevant Chinese agencies. An interagency team led by the International Trade Administration at the Commerce Department reviewed cases where the Chinese government failed to provide adequate protection and enforcement of IPR to U.S. businesses, and after an internal vetting process, sent approved cases to the Chinese government to facilitate their resolution. A number of cases were initially submitted to the Chinese through the Case Referral Mechanism, and at a high level meeting in 2006, Chinese Vice Premier Wu Yi committed to vigorously pursuing these cases. It seems under the Obama Administration that this program is not being fully utilized.

Addendum to Written Statement Submitted Thursday, April 26, 2012

As an addendum to materials provided in my written statement, it might be useful for the Subcommittee to consider the volume and characteristics of cases filed under the WTO dispute resolution process by the Administrations of George W. Bush and Barack Obama as but one indicator of the overall intensity of efforts to enforce the rights of U.S. companies facing violations of international trade rules.

Under President George W. Bush, the U.S. filed a total of 24 WTO cases. Of these 24 cases filed by the Bush Administration, 7 cases were filed against China, including the first IP-related cases filed against the Chinese. Under President Obama, the U.S. has filed 8 WTO cases in 3 ½ years. This includes the *China – Raw Materials case* filed in May 2009, in which most of the preparatory work was done under President Bush. It should be noted, however, that 6 of the cases brought by the Obama Administration have been against China. This equates to almost 3 cases a year during the eight years of the Bush Administration and 2 cases a year during the 3+ years of the Obama Administration, making it fair to say that the Obama Administration has been slightly less aggressive in terms of raising U.S. concerns in the WTO than the Bush Administration.

Written Testimony of

Horacio E. Gutiérrez
Corporate Vice President & Deputy General Counsel
Microsoft Corp.

before the

SUBCOMMITTEE ON INTELLECTUAL PROPERTY, COMPETITION, AND THE INTERNET
COMMITTEE ON THE JUDICIARY HOUSE OF REPRESENTATIVES

on

INTERNATIONAL PATENT ISSUES: PROMOTING A LEVEL PLAYING FIELD FOR AMERICAN INDUSTRY ABROAD

April 26, 2012

Chairman Goodlatte, Ranking Member Watt and Members of the Subcommittee, Microsoft greatly appreciates the opportunity to provide written testimony for inclusion in the record of this important hearing.

My name is Horacio E. Gutiérrez, and I am a Corporate Vice President and Deputy General Counsel for Microsoft, where I head the company's intellectual property ("IP") group. In that role, I oversee the acquisition, management, and use of Microsoft's extensive intellectual property portfolio, provide patent counseling to Microsoft business groups, and seek to manage infringement risks through proactive licensing.

Similar to the other companies represented at the hearing, Microsoft relies heavily on IP protection both in the U.S. and abroad. Currently, Microsoft invests more than $9 billion annually in R&D, making us one of the largest corporate funders of R&D in the world. This enormous expenditure is predicated on having sufficient IP protection to have an opportunity to earn a reasonable return on our investment. For this reason, Microsoft actively seeks patent protection in a significant number of jurisdictions across the globe and has built a world-wide portfolio that includes more than 31,700 issued patents and more than 38,000 pending applications.

Microsoft agrees with much of what was discussed at the hearing regarding the need for improved patent protection internationally. I will not belabor these points by repeating them here. However, I would like to comment upon one area of disagreement that was addressed in the written testimony. Microsoft disagrees with the criticism of a recent report issued by the Federal Trade Commission ("FTC") called "The Evolving IP Marketplace" (see http://www.ftc.gov/bc/workshops/ipmarketplace/) and

statements suggesting that the problem of "patent hold-up" in connection with standards-essential patents does not merit concern.

Firms benefit from having their inventions included in new information and communications technology standards, and in exchange for this, firms typically are required to make a promise: that if they have any patents that are "essential" to implementing a standard, they will make these patents available to all. In particular, these firms typically promise that they will make these "standards-essential patents" available to any firm that wishes to implement the standard on reasonable and nondiscriminatory terms ("RAND"). That way every firm can build products based upon the standard, secure in the knowledge that it can obtain a license to any essential patents. This means, for example, that every consumer can reasonably expect to be able to watch videos or connect to a wireless network regardless of the device they are using.

Every now and then a patent holder may break its promise to make its standards-essential patents available on reasonable and nondiscriminatory terms. This can create a lot of trouble for the international standards ecosystem. Once a standard like H.264 or 802.11 is widely adopted, firms have no choice but to implement the standard in their products. This is why antitrust enforcers and courts have taken a keen interest in attempts by patent holders to seek unreasonable licensing terms for access to their standards-essential patents and otherwise block their competitors from shipping products that implement industry standards if they do not accede to such license demands.

This concern, which was noted in the above-referenced report, is by no means a departure from the views previously expressed by antitrust regulators. Nor is this view unique to the FTC. In recent months, the European Commission and the U.S. Department of Justice have also highlighted concerns about the possibility that patent holders could threaten to block competitors from shipping their products as a way to extract patently unreasonable royalty payments.

A RAND commitment means that a reasonable license is always available to implementers of a standard. In fact, that is the whole reason that standard-setting organizations require them: they are a promise from the patent owner that the patent rights necessary for implementing a standard will be made available to all implementers at a reasonable price. Without such assurances from patent holders, implementing a standard would involve enormous liability risks, which would hinder broad adoption and use.

In the IT industry, such standards are absolutely critical to a product's viability. As noted recently by the European Commissioner for Competition, Commission Vice President Almunia:

> "Indeed, standardised technology is the basis for the IT industry to function. Different devices can exchange information and work with each other only thanks to commonly agreed standards.
>
> To build a smartphone one needs thousands of standard-essential patents. The holders of these patents have considerable market power and can effectively hold-up the entire industry with the threat of banning competitors' products from the market through injunctions for patent infringements.

By threatening to block competitors from offering their products to consumers, these companies can also make demands that their commercial partners would not accept under normal circumstances.

Using the threat of an injunction to force standards implementers to accept prices and terms that would be flatly rejected in a normal business negotiation is inconsistent with a RAND licensing commitment.[1] Beyond voicing concerns about this behavior, the European Commission has opened several investigations focused on suspected abuses of standards-essential patents.[2]

The DOJ and FTC have also repeatedly expressed concerns about the harm to competition resulting from such tactics.[3] And recognition of this problem has not been limited to antitrust regulators, but rather extends to courts, academics and business leaders. For example, the U.S. Court of Appeals for the Third Circuit in *Broadcom v. Qualcomm* (2007) held that:

> "[In some circumstances,] the patent holder is in a position to 'hold up' industry participants from implementing the standard. Industry participants who have invested significant resources developing products and technologies that conform to the standard will find it prohibitively expensive to abandon their investment and switch to another standard. They will have become 'locked in' to the standard. In this unique position of bargaining power, the patent holder may be able to extract supracompetitive royalties from the industry participants. *See In the Matter of Rambus, Inc.*, No. 9302, at 4 (F.T.C. Aug. 2, 2006), available at 2006 WL 2330117; Skitol Letter, supra, at 8; Majoras, supra, at *1; Masoudi, supra, at *3; *see also Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 476 (1992) (describing the lock-in that causes purchasers of expensive office equipment to tolerate supracompetitive service prices before changing brands); *Qualcomm Inc. v. Broadcom Corp.*, No. 05-CV-1958-B, 2007 WL 2296441, at *34 (S.D. Cal. Aug. 7, 2007) (characterizing such conduct as an attempt at 'holding hostage the entire industry desiring to practice the . . . standard').
>
> .... We hold that (1) in a consensus-oriented private standard setting environment, (2) a patent holder's intentionally false promise to license essential proprietary technology on FRAND terms, (3) coupled with an SDO's reliance on that promise when including the technology in a standard, and (4) the patent holder's subsequent breach of that promise, is actionable anticompetitive

[1] http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/12/172&format=HTML&aged=0&language=EN&guiLanguage=en.

[2] *See, e.g.,* http://europa.eu/rapid/pressReleasesAction.do?reference=IP/12/89&format=HTML&aged=0&language=EN&guiLanguage=e and http://europa.eu/rapid/pressReleasesAction.do?reference=IP/12/345&format=HTML&aged=0&language=EN&guiLanguage=en.

[3] *See* http://www.justice.gov/atr/public/press_releases/2012/280190.htm ("In practice, however, SSO F/RAND requirements have not prevented significant disputes from arising in connection with the licensing of SEPs, including actions by patent holders seeking injunctive or exclusionary relief that could alter competitive market outcomes"); http://www.ftc.gov/opa/2007/04/ipreport.shtm#ink ("[The] antitrust issues that may arise from collaborative standard setting when standards incorporate technologies that are protected by intellectual property ("IP") rights. These issues involve the potential for 'hold up' by the owner of patented technology after its technology has been chosen by the SSO as a standard and others have incurred sunk costs which effectively increase the relative cost of switching to an alternative standard").

> conduct. This holding follows directly from established principles of antitrust law and represents the emerging view of enforcement authorities and commentators, alike. Deception in a consensus-driven private standard-setting environment harms the competitive process by obscuring the costs of including proprietary technology in a standard and increasing the likelihood that patent rights will confer monopoly power on the patent holder. See *Rambus*, No. 9302, at 68 (holding that 'distorting [the SDO's] technology choices and undermining [SDO] members' ability to protect themselves against patent hold-up . . . caused harm to competition')."

Of particular concern to Microsoft is the fact that, the abuse of standards-essential patents to effectuate a hold-up appears to be increasing. In fact, Microsoft is currently the target of multiple patent infringement suits based on standards-essential patents relating to two of the most broadly used standards (the 802.11 WiFi standard and H.264, the encoding standard used by Blu-ray and for most Internet video). Despite having formally committed to license these patents to all implementers, the patent owner (Motorola Mobility) is now seeking to block Microsoft from shipping Windows and Xbox products that implement these common standards. This is part of an effort to obtain billions of dollars in royalties from Microsoft.

The royalties demanded are patently unreasonable (several thousand times the royalties charged by the patent pool created to license other patents essential to implementing H.264). But if Microsoft refuses to pay, it risks billions of dollars in lost revenues due to injunctions barring the sale of Windows and Xbox consoles in key markets. Liability and business risk of this magnitude are anything but hypothetical concerns. (In fact, two injunctions recently issued that would preclude Microsoft from selling the Windows operating system and Xbox game consoles in Germany.) To the contrary, the use of injunctions to extort commercially-unreasonable concessions from standards implementers imposes very real (and detrimental) harms not just for individual defendants but for the economy in general.

This behavior also harms consumers. For example, in the Xbox the 802.11 Wi-Fi functionality is embodied as part of a chip produced by Marvell that costs between $3 and $4. Motorola is demanding more than $4 in royalties—more than the cost of the entire chip in which the technology is embodied. Imagine if all the other patent owners with standard-essential patents made similar demands. Prices for consumer electronics products would increase to a point that most consumers could not afford them.

The solution to this problem is straightforward. A patent owner who has made a RAND commitment should be expected to live up to it. The patent owner should make its patents available, not try to use them to block competitors from offering their products to consumers. And if it refuses to do so, government intervention of some form is both necessary and appropriate to enforce the RAND commitment and to protect those who implemented a standard in reliance on a patent owner's commitment.

Microsoft strongly believes that this is an appropriate focus of antitrust enforcement efforts and that it warrants further scrutiny and discussion by other government entities, including Congress and the

courts. Accordingly, we would respectfully urge the members of this Subcommittee to consider further investigation of this important subject in its policymaking and oversight roles.

By electronic submission:

Written Testimony of the Biotechnology Industry Organization

Submitted to the

UNITED STATES HOUSE OF REPRESENTATIVES

COMMITTEE ON THE JUDICIARY

SUBCOMMITTEE ON INTELLECTUAL PROPERTY, COMPETITION

AND THE INTERNET

Hearing on: "International Patent Issues: Promoting a Level Playing Field

for American Industry Abroad"

April 26, 2012

The Biotechnology Industry Organization (BIO) is a non-profit organization with a membership of more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 States and a number of foreign countries. BIO's members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. The U.S. life sciences industry, fueled by the strength of the U.S. patent system, supports more than 7.5 million jobs in the United States, and has generated hundreds of drug products, medical diagnostic tests, biotech crops, and other environmentally-beneficial products such as renewable fuels and bio-based plastics. These products are literally helping to feed, fuel and heal the world. The majority of BIO's members are small companies that currently do not have products on the market. As such, BIO's members rely heavily on the strength and scope of their patents, both domestically and internationally, to generate the investment necessary to sustain their long product development cycle. On average, it takes more than 10 years to develop a biotech medicine from its inception to regulatory approval and market launch. The average, fully-capitalized cost of developing a new medicine has been estimated at $ 1.2 billion.

To fully understand what is needed to level the playing field for the biotechnology sector in international markets, one must understand the intellectual property (IP) needs of the

biotechnology sector. Biotechnology innovation requires predictable and effective upstream (early stage) and downstream (product) IP protection. Biotechnology innovation generally starts with an early laboratory discovery, and thus upstream protection helps to generate investment and interest in the further, applied research and development of the invention. Upstream protection includes broad patent eligibility for biotech innovations, consistent patent term, flexible licensing practices, and effective patent enforcement.

Downstream protection is just as important. As mentioned above, the research and development of a biological product can take decades and cost more than a billion dollars to complete. A significant portion of this time and money goes towards developing the regulatory data package that is required by the U.S. FDA, USDA, or similar foreign regulatory offices to approve the biotech product. Therefore, downstream protection for biotech products must include sufficient protection against foreign and domestic competitors relying on the innovator's data package to secure abbreviated approval of competitive products in such markets.

IP Challenges Faced by Biotechnology Companies Overseas

For BIO companies, pursuing international patent protection generally occurs early in the company and product's life cycle. All biotechnology companies understand that the products they hope to develop require robust patent protection abroad. Typical biotechnology inventions include modified cell lines, nucleic acids, proteins, monoclonal antibodies, vaccines, and modified plants and animals, some of which are not patentable in many major markets. Nevertheless, when small biotechnology companies seek access to capital to sustain their existence and development program, a central factor for valuation by investors is the strength of their IP portfolio, which must include, in almost every instance, patents or patent applications in at least the U.S. market and those of the United States' major foreign trading partners.

In fact, empirically we know that U.S. biotechnology companies are a large exporter of IP. U.S. companies are, by a wide margin, the largest originator of international biotechnology patents in all major markets.[1] Small biotechnology companies, which together hold approximately 80% of the development pipeline for new medicines, diagnostics and other bio-based products, play a significant part in this patenting activity.

[1] It appears that U.S. dominance as an originator of international patent applications is nowhere as pronounced as in the biomedical arts. For example, for the 2001-2005 timeframe, the 2008 WIPO World Patent Report lists the following numbers of foreign-filed patent families, by country of origin (top 2 countries):

Technology/Originating Country	United States	Japan
Biotechnology	32,139	7,094
Pharmaceuticals	43,317	7,738
Instruments – Medical Technology	57,902	17,611
Telecommunications	34,627	39,479
Semiconductors	20,431	48,369
Instruments - Optics	18,012	54,278
Machine tools	9,207	11,257

As products advance through development, biotech companies often need larger partners in the United States and abroad to develop their experimental products into a market-ready, approvable stage. And even for market-ready products, U.S.-based biotech companies often find it easier to partner with a foreign affiliate who will secure foreign regulatory approval and market the invention in a foreign market, rather than establishing their own overseas sales force. In each case, such partnering depends on robust patent rights that will secure all partners a return on investment.

BIO's members often bear the initial burden of procuring this international patent protection, since patent rights must typically be sought before such partnerships develop, and near-simultaneously in the United States and in foreign jurisdictions. Early international filing enables these smaller companies to partner with larger companies later in their product life cycle to export their products internationally. It is generally not an option for biotech companies to wait to secure foreign patent protection until after such partnerships, as possible forfeiture of patent rights is too great a risk in foreign "absolute novelty" jurisdictions. It is imperative that biotechnology companies plan ahead, even at their inception, to ensure that over the ensuing 10 to 15 years they have the opportunity to partner with larger companies to export their products internationally.

What then are the challenges biotechnology companies face when filing for patents internationally? First and foremost, international patent procurement is expensive. A recent *Nature* article finds that "obtaining a valid patent in most of Europe can cost up to $126,000, the majority spent on validating the patent in each country and translation."[2] The European Commission reports that the average costs of patent filing, validation, and translation in the European Union (EU) is approximately €35,000 (≈$46,000) compared to the average cost in the United States, which is €1,850(≈$2,400).[3]

It is often difficult for biotechnology companies to limit these costs due to the inherent uncertainty surrounding biotech innovation and patenting. As noted above, biotechnology companies must patent early in their development life cycles, while simultaneously trying to predict which patents will be valuable in 10 or more years and which patents will not be so valuable. In other words, biotechnology companies deal with slowly-developing technology that does not allow them to decide to abandon or maintain a family of patent applications before the real prosecution costs kick in. For example, a biotech company that files a U.S. patent application today (and a PCT application one year from now) has only 30 months to decide whether to abandon the application if it wants to avoid the cost of entering the national stage in a number of foreign countries. Including translation costs, the aggregate expense of entering the national stage in Japan, Korea, Europe, Australia, and the NAFTA countries can easily exceed $100,000; if the "BRIC" countries (Brazil, Russia, India and China) are added, costs can double. Thirty months may be enough time to allow other industries to decide whether to spend $200,000 on a patent application, but in biotech that's too soon to make an informed decision.

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[2] "Obtaining a valid patent in most of Europe can cost up to $126,000, the majority spent on validating the patent in each country and translation." See http://www.nature.com/nbt/journal/v30/n3/full/nbt0312-200.html.

[3] See http://ec.europa.eu/europe2020/pdf/cm012012_background_en.pdf

Likewise, even if the company defers foreign examination where that is an option, annuities can accumulate to more than negligible amounts. Foreign attorney fees, once prosecution begins, add another substantial layer of cost. Many such costs must be incurred before a biotech company is able to decide whether to maintain or abandon the application. BIO has numerous member companies that are many years away from market approval, but that must, every year, reserve hundreds of thousands of their scarce dollars for purposes of maintaining their ability to secure patent rights. As a result, patent filing and prosecution costs abroad are often far from negligible relative to their R&D budgets. Uniformly, such companies would prefer to spend their money to advance their science to develop a commercial product.

Biotechnology companies also face unique challenges as foreign biotechnology patent prosecution can be complicated and is subject to greater non-uniformity of the law than in many other technologies. What is permissible patent claim scope can differ significantly from country to country, which complicates and increases the cost of international patent filing for biotech inventions. For example, examiners in China, Japan, and elsewhere impose onerous data requirements not found in the United States or Europe, which can restrict the scope of the patent. This restricted scope makes it easier for competitors to design around the patent. Other examination inequities include interpreting enablement requirements to restrict patent protection to just the working examples of the case (e.g., in China). Other countries like Canada require substantial clinical evidence before filing a drug patent application and extensive data to prove patentability or operability – requirements that are not found in other major industrialized nations.

In addition to restrictions on patent scope, it is often very difficult to obtain patent protection in a timely manner in some countries. As an example, in India, there is a lengthy pre-grant opposition system, which can delay patent issuance by several years. Once a patent is issued, the same patent then can be the subject of a post-grant opposition. In the United States, some of the patent term lost due to administrative delays prior to issuance can be recovered through patent term extensions. Moreover, for U.S.-regulated products, there is patent term restoration for time lost during the regulatory review period. However, neither of these remedies is available in many other countries (including developed countries like Canada), where patent backlogs and other procedural and regulatory requirements significantly reduce patent term for biotechnology inventions. Such lost patent term significantly disadvantages companies with long development times and complex products such as biopharmaceuticals.

Furthermore, some countries like India and China require that a patent be "worked" in their country to maintain the property right, and will issue a compulsory license if the patent owner fails to satisfy this condition. The recent Bayer compulsory license case in India clearly shows how far some countries will take such matters, as the Indian Controller General stated that **all** patents (not just drugs) must be "manufactured to a reasonable extent in India" and that "mere importation cannot amount to working of a patented invention."[4] Given how complicated the production of biologic medicines and other biotech products can be, such provisions are ripe for abuse to the detriment of U.S. companies and citizens.

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[4] See http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf

Finally, others countries refuse to allow patentability for biotechnology inventions altogether. Countries like Brazil refuse to allow patents for claims to "isolated" DNA, proteins, antibodies or "recombinant" inventions, and require that medical inventions go through two-layers of patenting review – by both the patent office and the regulatory office in charge of approving new medicines. Similarly, some countries like India impose "efficacy" requirements applied only to medical innovations without sufficient rationale.[5] Other countries refuse to patent method of medical treatment claims. While many countries will claim legitimate reasons for refusing to patent such inventions, such restrictions do not apply when innovators from those same countries apply for patents in the United States,[6] thus creating an uneven international playing field for U.S. companies.

These are just some of the many patent inequities that biotechnology companies face when trying to protect their innovations.[7] Without procedural and substantive patent law harmonization, these problems are likely to continue to negatively impact the development and growth of U.S. biotechnology companies. As mentioned above however, patent protection is not the only type of IP that is necessary for the American biotechnology industry succeed globally. Sufficient protection for the massively expensive data that is required by regulatory authorities abroad is also critical.

BIO notes that some elements of harmonization can be achieved through bilateral and regional trade agreements. One such agreement in particular, the Trans-Pacific Partnership Agreement or "TPP," is currently being negotiated by the United States and several key Asia Pacific countries. Such a regional agreement can serve as the basis for future agreements in emerging markets and as such has the potential to lay the framework for a harmonized IP system. In this agreement and others, the United States should advocate for IP provisions that are consistent with U.S. law, including the newly-enacted 12 years of data protection for biologics. BIO urges this Subcommittee's engagement in the process to ensure that the outcome includes a strong IP framework for U.S. innovators, consistent with U.S. law and international trade principles of reciprocity.

On behalf of BIO, I would like to thank the Subcommittee Chairman and Ranking Member for the opportunity to submit this written testimony for the record. BIO urges that this Subcommittee and the United States Congress as a whole continue its efforts to improve IP protection abroad for American innovation, and to encourage predictability of patent rights across multiple foreign jurisdictions. Simply put, a more harmonized system can help to ensure that an applicant in one major country patent examining office is able to expect that the same patent application with the same claims would obtain the same examination result in another

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[5] Novartis is currently litigating a case in which the company was denied a patent on a drug formulation for "efficacy" reasons even though the drug formulation "is widely recognized as one of the major medical breakthroughs of the 20th century." See Novartis Fact Sheet: http://www.novartis.com/downloads/newsroom/glivec-information-center/Fact_vs_fiction_of_Glivec_India_Case.pdf

[6] In 2010, Chinese entities filed 8,162 patent applications in the United States, and Indian entities filed 3,789 such applications. See http://www.bio.org/advocacy/letters/biotech-ip-issues-around-world-bios-2012-special-301-reporthttp://www.wipo.int/ipstats/en/statistics/patents/

[7] For more international IP challenges facing biotechnology companies see Biotech IP Issues Around the World: BIO's 2012 Special 301 Report

major examining office. Such an achievement will provide U.S. companies and individual inventors a true level playing field internationally.

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